AGILE THERAPEUTICS INC
Form S-1/A
April 17, 2014

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FINANCIAL STATEMENTS

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As filed with the Securities and Exchange Commission on April 17, 2014

Registration Statement No. 333-194621

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 1
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)

Copies to:

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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.

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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 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 April 17, 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 12.

	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

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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.

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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.

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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

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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

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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

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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 $118.3 million as of December 31, 2013.

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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

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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.

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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 73,954 shares of common stock outstanding as of December 31, 2013 and shares of common stock issuable upon conversion of all currently outstanding shares of our convertible preferred stock 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;
- 831,158 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 at a weighted average exercise price of $4.81 per share;
- 25,002 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2013, at an exercise price of $15.00 per share; and

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shares of common stock available for future grant under our 2014 Incentive Compensation Plan as of December 31, 2013.

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; and

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

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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. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with "Management's Discussion 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,		Period from Inception (December 22, 1997) to December 31, 2013
	2012	2013	
	(In thousands, except share and per share data)		
Statement of operations data:			
Operating expenses:			
Research and development	$ 17,387	$ 9,154	$ 86,218
General and administrative	5,930	3,574	26,344
Total operating expenses	23,317	12,728	112,562
Loss from operations	(23,317)	(12,728)	(112,562)
Total other income (expense)	57	(1,592)	(265)
Loss before benefit for income taxes	(23,260)	(14,320)	(112,827)
Benefit from income taxes			673
Net loss	(23,260)	(14,320)	(112,154)
Beneficial conversion charge	(600)		(6,160)
Net loss available to common shareholders	$ (23,860)	$ (14,320)	$ (118,314)
Weighted average basic and diluted common shares outstanding	28,227	35,347	
Loss per common share basic and diluted	$ (845.29)	$ (405.14)	

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	As of December 31, 2013		
	Actual	Pro Forma(1)	Pro Forma as Adjusted(2)(3)
		(In thousands)	
Balance sheet data:			
Cash and cash equivalents	$ 2,120	$	$
Total assets	14,405		
Total current liabilities	6,844		
Long term debt, less current portion	9,770		
Convertible preferred stock	69,233		
Deficit accumulated during the development stage	(118,314)		
Total shareholders' equity (deficit)	(71,442)		

(1) Pro forma amounts reflect (i) the net exercise of all outstanding warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock into shares of preferred stock that will subsequently be converted into shares of common stock, assuming an initial public offering price of $ (the midpoint of the price range set forth on the cover page of this prospectus), (ii) 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, and (iii) the conversion of all our outstanding shares of convertible preferred stock into an aggregate of shares of our common stock.

(2) Pro forma as adjusted amounts reflect the pro forma conversion adjustments described in footnote (1) above, as well as the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets and total stockholders' equity by $, assuming the number of shares offered by us as stated on the cover page of this prospectus remain unchanged and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $, assuming the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

You should carefully consider the risk factors set forth below as well as the other information contained in this prospectus before investing in our common stock. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. In such a case, you may lose all or part of your investment. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently view to be immaterial may also materially adversely affect our business, financial condition or results of operations.

Risks Related to the Clinical Trial Process and Regulatory Approval for Our Product Candidates

We have not obtained regulatory approval for any of our product candidates in the United States or any other country.

We currently do not have any product candidates that have gained regulatory approval for sale in the United States or any other country, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval to market each product candidate from the U.S. Food and Drug Administration, or FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities.

We have previously conducted two Phase 3 clinical trials for Twirla, and we filed a new drug application, or NDA, with the FDA for Twirla in April 2012. The FDA issued a Complete Response Letter, or CRL, in February 2013, identifying certain issues, including a request for additional clinical data, quality information and chemistry, manufacturing and controls information, which must be addressed before approval can be granted. Accordingly, we are gathering the requested information and intend to conduct an additional Phase 3 clinical trial for Twirla, which is expected to commence enrollment during the third quarter of 2014. The FDA may also re-inspect our manufacturing partner's facilities before approval can be granted. Although we met with the FDA in October 2013 to discuss our new Phase 3 clinical trial and received substantial written comments from the FDA in February 2014, we have not sought and have not obtained agreement with the FDA on a special protocol assessment regarding the new Phase 3 trial. We cannot predict whether our additional Phase 3 clinical trial or any future trials we may conduct will be successful or whether regulators will agree with our conclusions regarding the results of these trials or any clinical trials we have conducted to date.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In the United States, it is necessary to submit an NDA to obtain FDA approval. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication, although we may partially rely on public information or the FDA's prior approval of

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similar products. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA may further inspect our manufacturing facilities to ensure that the facilities can manufacture our product candidates and our products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approval, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. Even if our product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies, or REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our ability to market to our full target market will be

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reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of our current or future product candidates.

Failure can occur at any stage of clinical development. If the clinical trials for Twirla or any of our current or future product candidates are unsuccessful, we could be required to abandon development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, adverse events may occur or other risks may be discovered in our planned Phase 3 clinical trial for Twirla that would cause us to suspend or terminate the clinical trial. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the subject populations and the rates of dropout among clinical trial subjects. Our future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for our product candidates. For example, we received a CRL from the FDA with respect to an NDA previously filed for Twirla, in which the FDA requested, among other items, additional Phase 3 clinical data to support the application. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trials may not be successful.

Flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We have limited experience in designing contraceptive clinical trials and may be unable to design and execute clinical trials to support regulatory approval of our product candidates. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts for a product candidate.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to subjects. Furthermore, regulatory agencies, Institutional Review Boards, or IRBs, or data safety monitoring boards may at any time order the temporary or permanent discontinuation of our clinical trials or request that we cease using certain investigators in the clinical trials if such regulatory agencies or boards believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to subjects. Since our inception, we have not voluntarily or involuntarily suspended or terminated a clinical trial due to unacceptable safety risks to subjects.

If the results of the clinical trials for our current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of our product candidates will be materially adversely affected. For example, in the CRL that we received from the FDA in connection with the NDA previously filed for Twirla, one of the FDA's comments was that acceptable evidence of efficacy was not demonstrated, as measured by Pearl Index, or PI. Specifically, in our two completed Phase 3 trials, the PI was higher than that seen in registration trials for previously approved hormonal contraceptives. Most experts seem to agree that inconsistent or incorrect use is

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a major contributor to the increased PI seen in more recent contraceptive trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer-term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier preclinical studies have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. Our planned Phase 3 trial for our primary product candidate, Twirla, may not produce the results that we expect, or the FDA may interpret the data differently than we do.

In addition to the circumstances noted above, we may experience numerous unforeseen events that could cause our clinical trials to be delayed, suspended or terminated, or which could delay or prevent our ability to receive regulatory approval for or commercialize our product candidates, including:

- Clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or implement a clinical hold;
- The number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate. For instance, we experienced a high withdrawal rate in our two completed Phase 3 clinical trials for Twirla;
- Our third party contract research organization, or CRO, or study sites may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all. For instance, investigator compliance with study procedures was an issue that we encountered in our two completed Phase 3 clinical trials for Twirla;
- Regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;
- We may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CRO;
- We may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- We may elect or be required to suspend or terminate clinical trials of our product candidates based on a finding that the subjects are being exposed to health risks, or due to other reasons;
- The cost of clinical trials for our product candidates may be greater than we anticipate;
- The supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- There may be changes in government regulations or administrative actions;

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Our product candidates may have undesirable adverse effects or other unexpected characteristics;

We may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

We may not be able to demonstrate that a product candidate provides an advantage over current standards of care or future competitive therapies in development; and

There may be changes in the approval policies or regulations that render our data insufficient for approval.

If we elect or are required to suspend or terminate a clinical trial for any of our product candidates, or our product candidate development is otherwise delayed, our development costs may increase, our commercial prospects will be adversely impacted, any periods during which we may have the exclusive right to commercialize our product candidates may be shortened and our ability to generate product revenues may be delayed or eliminated.

We expect to conduct additional clinical trials in the future for Twirla and our other product candidates. Subject enrollment, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

Size and nature of the subject population;

Proximity of subjects to clinical sites and the number of sites;

Effectiveness of publicity created by clinical trial sites regarding the trial;

Eligibility and exclusion criteria for the trial;

Design of the clinical trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;

Competing clinical trials;

Clinician and subject perceptions as to the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for the indications we are investigating;

Subjects' ability to comply with the specific instructions related to the trial protocol, proper documentation and use of the drug product. For instance, in our Phase 3 clinical trials, there was a high rate of subject noncompliance;

Inability to obtain or maintain subject informed consents;

Risk that enrolled subjects will drop out before completion; and

Subject's relationship with her partner.

Furthermore, we plan to rely on a CRO and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we may have agreements governing their committed activities, we have limited influence over their actual performance. Additionally, the CRO and clinical trial sites may have business, regulatory, personnel or other issues that keep us from satisfactorily completing our clinical trials. Any delays or unanticipated problems during clinical trials, such as additional monitoring of clinical trial sites, slower than anticipated enrollment in our

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clinical trials or subjects dropping out of or being excluded from participation in our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and harm our business.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our product candidates if regulatory authorities require additional time or studies to assess the safety and efficacy of our product candidates.

We may be unable to initiate or complete development of our product candidates on schedule, if at all. The timing for the completion of the studies for our product candidates other than Twirla will require funding beyond the proceeds of this offering. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of Twirla, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our product candidates. Additional delays may result if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Studies required to demonstrate the safety and efficacy of our product candidates are time consuming, expensive and together take several years or more to complete. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many factors, including:

Our inability to obtain sufficient funds required for a clinical trial;

Regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;

Regulatory questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products;

Clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;

Failure to reach agreement with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;

Our inability to enroll or retain a sufficient number of subjects who meet the inclusion and exclusion criteria in our clinical trials;

Our inability to conduct our clinical trials in accordance with regulatory requirements or our clinical trial protocols;

Unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of our product candidates during clinical trials;

Failure to meet the level of statistical significance required for approval;

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Any determination that a clinical trial presents unacceptable health risks to subjects;

Lack of adequate funding to commence or continue our clinical trials due to unforeseen costs or other business decisions;

Our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

Our inability to identify and maintain a sufficient number of sites, many of which may already be engaged in other clinical trial programs, including other clinical trials for the same indications targeted by our product candidates;

Our inability to obtain approval from IRBs to conduct clinical trials at their respective sites;

Our inability to timely obtain from our third party manufacturer sufficient quantities or quality of the product candidate or other materials required for a clinical trial;

We may be unable to obtain approval for the manufacturing processes or facilities of the third party manufacturer with whom we contract for clinical and commercial supplies;

We may have insufficient funds to pay the significant user fees required by the FDA upon the filing of an NDA; and

We may have difficulty in maintaining contact with subjects, resulting in incomplete data.

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

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities or conduct additional studies to reflect these changes. Amendments and additional studies may require us to resubmit clinical trial protocols to Institutional Review Boards and regulatory authorities for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. For example, the FDA issued a CRL in response to our NDA for Twirla requesting, among other items, an additional Phase 3 clinical study, which will delay our ability to obtain regulatory approval for that product candidate. We may also experience delays due to changes in regulatory requirements and guidance, which may require protocol amendments or the conduct of additional studies. These amendments and additional studies may require regulatory or IRB approval. The approval and conduct of these studies may delay, limit or preclude regulatory approval for our product candidates. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. Significant clinical

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trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

Our product candidates may have undesirable adverse effects, which may delay or prevent regulatory approval or, if approval is received, require our products to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen adverse effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. In the combined safety population of our completed Phase 3 trials, there were a total of 22 serious adverse events, or SAEs, of which 16 occurred in the Twirla cohort, which had approximately 2.3 times as many subjects as the oral contraceptive comparator cohort. Three of the 16 SAEs in the Twirla cohort (0.2% of the overall Twirla safety population) were considered to be possibly related to Twirla, and included one drug overdose with Benadryl, one case of uncontrollable nausea and vomiting and one instance of deep vein thrombosis. In addition to the SAEs described above, some subjects taking Twirla experienced non-serious adverse events, such as nausea, headache, application site irritation and breast tenderness. Subjects receiving the oral contraceptive comparator also experienced non-serious adverse events such as nausea, headache and breast tenderness, though at different rates.

Any undesirable adverse effects that may be caused by our product candidates could interrupt, delay or halt clinical trials and could result in more restrictive labeling or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. Adverse effects could also impact subject recruitment or the ability or willingness of enrolled subjects to complete the trial, or result in product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if any of our product candidates receive regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

We may suspend marketing of, withdraw or recall the product;

Regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication, or other labeling changes;

Regulatory authorities may withdraw their approval of the product;

Regulatory authorities may seize or detain the product or seek an injunction against its manufacture or distribution;

The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;

The FDA may require the establishment or modification of a REMS or a comparable foreign authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such adverse

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effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on us;

We may be required to conduct additional trials;

We may be required to change the way that the product is administered;

We may be subject to litigation or product liability claims, fines, injunctions or criminal penalties;

Regulatory authorities may impose additional restrictions on marketing and distribution of the product; and

Our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale.

Our development and commercialization strategy for Twirla depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products containing Ethinyl Estradiol and Levonorgestrel based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. We have submitted an NDA for Twirla under Section 505(b)(2) and as such the NDA relied, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products containing ethinyl estradiol, or EE, and levonorgestrel, or LNG and published scientific literature for which we have not received a right of reference. We received a CRL in response to our Section 505(b)(2) NDA for Twirla, in which the FDA requested, among other things, that we conduct an additional Phase 3 clinical trial. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for Twirla, the FDA may require us to perform additional clinical trials or measurements to support approval over and above the clinical trials that we have already completed and the additional clinical trial we currently plan to commence during the third quarter of 2014. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA

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changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our product candidates, including Twirla.

Risks Related to Our Financial Position and Need for Capital

We have never been profitable. Currently, we have no products approved for commercial sale, no source of revenue and we may never become profitable.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have no products approved for commercial sale and to date have not generated any revenue from product sales. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of and obtain the necessary regulatory approvals for our product candidates. We have been engaged in developing Twirla and our Skinfusion technology since our inception. To date, we have not generated any revenue from Twirla, and we may never be able to obtain regulatory approval for the marketing of Twirla. Further, even if we are able to gain approval for and commercialize Twirla or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our ability to generate product revenue depends on a number of factors, including our ability to:

Successfully complete clinical development of, and receive regulatory approval for, our product candidates;

Set an acceptable price for our products, if approved, and obtain adequate coverage and reimbursement from third party payors;

Obtain commercial quantities of our products, if approved, at acceptable cost levels; and

Successfully market and sell our products, if approved, in the United States and abroad.

In addition, because of the numerous risks and uncertainties associated with product candidate development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or other regulatory authorities to perform studies in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products.

Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenues from the sale of our products, if approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or obtain additional funding, or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future.

We have incurred losses in each year since our inception in December 1997. Our net losses were $23.9 million for the year ended December 31, 2012 and $14.3 million for the year ended December 31, 2013. As of December 31, 2013, we had a deficit accumulated during the development stage of $118.3 million.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur expenses without corresponding revenues until we are able to obtain regulatory approval and subsequently sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We expect to incur increased expenses as we commence our additional Phase 3 clinical trial for Twirla, respond to the CRL and supplement our NDA with the results of the trial, advance our other product candidates and expand our research and development programs. To date, we have financed our operations primarily through the sale of convertible preferred stock and convertible debt. Our product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

Assuming we obtain FDA approval, we expect that our expenses will increase as we prepare for the commercial launch of Twirla. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses may increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about 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. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted a majority of our resources to developing Twirla, but this product candidate cannot be marketed until regulatory approvals have been obtained. Meaningful revenues will likely not be available until and unless Twirla or any of our current or future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. If we successfully complete this offering, based upon our currently-expected level of operating expenditures, we expect to be able to fund our operations through the first quarter of 2016. This period could be shortened if there are any significant increases in planned or actual spending on development programs or more rapid

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progress of development programs than anticipated. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

If we fail to obtain the capital necessary to fund our operations, we may be unable to obtain regulatory approval of or commercialize Twirla in the United States and we could be forced to share our rights to commercialize Twirla with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our development and commercialization efforts for Twirla. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to Twirla with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Based on our current operating plans, and after giving effect to the receipt of the estimated net proceeds of this offering, we believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs through the first quarter of 2016. Our cash and cash equivalents were $2.1 million as of December 31, 2013. We anticipate requiring additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our loan agreement and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

As of December 31, 2013, we had $15 million of principal indebtedness outstanding under our loan and security agreement with Oxford Finance LLC, or Oxford. The loan agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, change our line of business, liquidate or dissolve, enter into any change in control transaction, merge or consolidate with any other entity or acquire all or substantially all the capital stock or property of another entity, incur additional indebtedness, incur certain types of liens on our property, including our intellectual property, pay any dividends or other distributions on our capital stock other than dividends payable solely in capital stock or redeem our capital stock. Our business may be adversely affected by these restrictions on our ability to operate our business.

The term loan is secured by substantially all of our property other than our intellectual property. We are currently required to make interest-only payments through April 2014. Based upon certain conditions, the interest-only period may be extended through January 2015. However, we cannot assure you that we will fulfill these conditions, and therefore we may be required to make payments of both principal and interest on the term loan beginning on May 1, 2014. The term loan bears interest at a fixed rate of 9.2% per annum and matures on July 1, 2017, assuming the successful completion of this offering.

Additionally, we may be required to repay the outstanding indebtedness under the term loan if an event of default occurs under the loan agreement. Under the loan agreement, an event of default will occur if, among other things, we fail to make payments under the loan agreement; we breach any of our covenants under the loan agreement, subject to specified cure periods with

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respect to certain breaches; Oxford determines in good faith that we are unable to satisfy our obligations under the loan agreement as they become due and that our principal investors do not intend to fund amounts necessary to satisfy such obligations; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit Oxford to accelerate the maturity of such indebtedness or that could have a material adverse effect on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Oxford could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

We will need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. From our inception to December 31, 2013, we have cumulative net cash flows used by operating activities of $106.8 million. We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. We will need to obtain additional financing to conduct additional trials for the approval of our product candidates if requested by regulatory authorities, and to complete the development of any additional product candidates we might acquire. Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- Progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our planned and potential future clinical trials;
- Time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;
- Our ability to successfully commercialize our product candidates, if approved;
- Amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- Sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of expanding our marketing and sales capabilities;
- Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- Cash requirements of any future acquisitions or the development of other product candidates;

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Costs of operating as a public company;

Time and cost necessary to respond to technological and market developments; and

Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

We believe that the estimated net proceeds from this offering, together with existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through the first quarter of 2016. We expect that these funds will not be sufficient to enable us to complete all necessary development of our product candidates other than Twirla or commercially launch Twirla or our other current product candidates. Accordingly, we will be required to obtain further funding through other public or private offerings, debt financing, collaboration or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

Raising additional capital may cause dilution to our existing stockholders or restrict our operations.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. The sale of additional equity or convertible debt securities could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient

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amounts or on terms acceptable to us, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our common stock to fall.

We are a development stage company which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a development stage company. We were incorporated and commenced active operations in 1997. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and developing our product candidates. We have not yet demonstrated our ability to successfully complete a Phase 3 registration trial for, obtain regulatory approval of or manufacture on a commercial scale any of our product candidates, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a development stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a focus on product candidate development to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Relating to the Commercialization of Our Product Candidates

We are substantially dependent on the commercial success of Twirla.

Assuming FDA approval, Twirla will be the first product that we commercialize. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Twirla. If Twirla or any other product that we commercialize in the future do not gain an adequate level of acceptance among physicians, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Twirla, and any other product that we commercialize, by physicians, patients and third party payors will depend on a number of factors, some of which are beyond our control, including:

- Efficacy, safety and other potential advantages of our product candidates in relation to alternative treatments;
- Relative convenience and ease of administration of our product candidates;
- Availability of adequate coverage or reimbursement of our product candidates by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;
- Prevalence and severity of adverse events associated with our product candidates;
- Cost of our product candidates in relation to alternative treatments, including generic products;
- Extent and strength of our third-party manufacturer and supplier support;
- Extent and strength of our marketing and distribution support;
- Limitations or warnings contained in our product's FDA approved labeling; and
- Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan.

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For example, if Twirla is approved by the FDA, physicians and patients may not be immediately receptive to a transdermal contraceptive system, as opposed to a pill or any other method, and may be slow to adopt it as an accepted treatment for the prevention of pregnancy. In addition, even though we believe Twirla has significant advantages over other treatment options, because no head-to-head trials comparing Twirla to the competing approved patch product have been conducted, the prescribing information approved by the FDA may not contain claims that Twirla is safer or more effective than the currently approved patch product, or other claims that may be necessary for successful marketing of Twirla. Accordingly, we will not be permitted to promote Twirla, if approved, for any comparative advantages to the currently marketed contraceptive patch. The availability of numerous inexpensive generic forms of contraceptive products may also limit acceptance of Twirla among physicians, patients and third party payors. If Twirla does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate significant product revenues or become profitable.

It will be difficult for us to profitably sell Twirla, if approved, or any other product that we obtain marketing approval for in the future if coverage and reimbursement for such product is limited.

Market acceptance and sales of Twirla, if approved, or any other product that we obtain marketing approval for in the future, will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for approved medications. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage or reimbursement will be available for Twirla, if approved, or any other product that we obtain marketing approval for in the future and, if coverage is available, we cannot be sure of the level of reimbursement. Reimbursement may impact the demand for, or the price of, Twirla, if approved, and any other products that we obtain marketing approval for and commercialize. Numerous generic products may be available at lower prices than branded therapy products, such as Twirla, which may also reduce the likelihood and level of reimbursement for Twirla or other products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize Twirla, if approved, or any other product for which we obtain marketing approval.

If we are unable to establish effective marketing and sales capabilities for Twirla, if approved, or enter into agreements with third parties to market and sell Twirla, we may be unable to generate product revenues.

We are seeking approval for Twirla from the FDA for a contraception indication. Assuming successful completion of our additional Phase 3 trial by the end of 2015, we plan to submit a complete response to the FDA that will include additional clinical trial results to our NDA in early 2016. Assuming a six-month review by the FDA, we could receive a decision late in 2016. We intend to launch Twirla as soon as possible following receipt of approval from the FDA, if granted. However, we cannot assure you that the FDA will approve Twirla or that the FDA's timeline for review will be within six months. Following our original submission of the NDA, we received a CRL from the FDA requesting, among other things, additional Phase 3 data. Assuming timely and

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successful completion of this additional Phase 3 study, and other items, and ultimate FDA approval, we expect to make Twirla available by prescription in the United States in the fourth quarter of 2016.

At present, we have no sales personnel and a limited number of marketing personnel. We do not intend to begin to hire additional marketing personnel until shortly prior to submission of our revised NDA or establish our own sales force or engage a contract sales organization in the United States until shortly prior to FDA approval of Twirla. At the time of our anticipated commercial launch of Twirla, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Twirla in the United States.

We may not be able to establish our own sales force or a contract sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize Twirla, if approved, in the United States without strategic partners or licensees include:

- Our inability to timely recruit and retain adequate numbers of effective sales and marketing personnel;
- The inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe Twirla;
- The lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- The costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- Liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements; and
- Unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing Twirla, which would adversely affect our business, operating results and financial condition.

If we intend to commercialize Twirla outside the United States, we will likely enter into collaboration agreements with pharmaceutical partners, and we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend on the success of the efforts of these third parties.

To the extent that we rely on, or partner with, third parties to commercialize Twirla, if approved, or any other product candidate for which we obtain marketing approval in the future, we may receive less revenue than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. In the event that we are unable to partner with a third party marketing

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and sales organization, our ability to generate product revenues may be limited in the United States, internationally or both.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of Twirla and possibly other product candidates in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

- Differing regulatory requirements in foreign countries including, among others, requirements relating to drug approvals, reimbursement and sales and marketing practices;
- Potentially reduced protection for intellectual property rights;
- The potential for so-called parallel importing, which is when a local seller, faced with higher local prices, opts to import goods from a foreign market with lower prices, rather than buying them locally;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees traveling and working abroad;
- Foreign taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other risks incident to doing business in another country;
- Workforce uncertainty in countries where labor unrest is more common than in the United States;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, tsunamis, hurricanes and fires.

These and other risks may materially adversely affect our ability to develop and commercialize products in international markets and may harm our business.

Even if we receive regulatory approval for Twirla, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

The commercial success of Twirla in any indication for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the contraceptive market landscape as well as acceptance and uptake of Twirla by physicians, patients and third-party payors.

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Risks related to the contraceptive market landscape include:

- The prescription contraceptive market could experience a decrease in growth or negative growth if fewer women choose to use hormonal contraception;
- The perceived safety of hormonal contraceptives could be negatively affected by media reports of adverse effects and advertisements for class action lawsuits due to adverse effects;
- Price pressures from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the contraceptive market comprised of generic products could continue to increase, making introduction of a branded contraceptive difficult and expensive;
- Competition in the contraceptive market could increase, with the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;
- Competition from generic contraceptive products could increase as additional generic contraceptives receive FDA approval;
- Implementation of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effect on pharmaceutical coverage, reimbursement and pricing could limit our revenue; and
- Access to the prescriber universe, particularly obstetrics and gynecology physicians, could be limited, decreasing our ability to promote Twirla efficiently.

The degree of acceptance and uptake of Twirla, if approved, by physicians, patients and third-party payors will depend upon a number of factors, including:

- The level of contraceptive effectiveness of Twirla demonstrated in our clinical trials;
- The incidence and severity of adverse effects associated with Twirla;
- Limitations on use or warnings contained in FDA-approved labeling;
- Acceptability to patients of the appearance and feel of Twirla;
- Willingness of patients to try a new contraceptive and to use a transdermal patch as their form of contraception;
- Willingness of physicians to prescribe a contraceptive patch in light of safety issues and restrictive labeling of the currently marketed contraceptive patch;

The cost of Twirla to the patient, as compared to other contraceptive products and methods;

Our ability to obtain and maintain sufficient third party coverage or reimbursement for Twirla from private health insurers, government healthcare programs (including Medicare, Medicaid and 340B Clinics) and other third party payors; and

The effectiveness of our or any future collaborators' sales and marketing strategies.

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In addition, even if we obtain regulatory approval, the timing of an approval may reduce our ability to commercialize Twirla successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render Twirla not commercially viable. For example, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, including REMS, or may approve Twirla with a label that contains fewer, or more limited, indications than requested, warnings, precautions or contraindications, including black box warnings, and the label may not include the claims necessary or desirable for the successful commercialization of Twirla. Any of the foregoing scenarios could materially harm the commercial prospects for Twirla.

If Twirla is approved, but does not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate physicians, patients and third party payors on the benefits of Twirla may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors and become profitable, if the market for hormonal contraceptives fails to achieve expected future growth or decreases, we may not generate sufficient revenue or sustain profitability.

The proportion of the contraceptive market that is made up of generic products could continue to increase, making introduction of a branded contraceptive difficult and expensive.

The proportion of the U.S. market that is made up of generic products has been increasing over time. In 2005, generic contraceptive products held 47% of prescription volume and 34% of sales and, by 2011, those values had risen to 68% and 44%, respectively. As of September 2013, 73% of the prescription volume and 45% of sales of combined hormonal contraceptives, or CHCs, in the U.S. were generated by generic products. If this trend continues, it may be more difficult to introduce Twirla, if approved, as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Twirla in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we are unable to introduce Twirla at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payors for Twirla, or if patients are unwilling to pay any price differential between Twirla and a generic contraceptive, our revenues will be limited. For example, in light of the introduction of the generic version of the Ortho Evra product by Mylan Inc. in April 2014, in order to be competitive and gain market share, we may increase the rebates available to commercial and governmental payors or we may provide incentives to consumers, such as coupons or rebates, in order to make up for the difference in the co-payment for Twirla and the generic patch product.

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Physicians, patients and payors may not adopt a new contraceptive patch due to concerns based upon the prior experience with or perception of the currently marketed contraceptive patch.

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The following is a brief history of the Evra market experience:

Evra had rapid uptake in the contraceptive market, achieving a 10% share of the CHC market by September 2003. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms.

Following the approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA.

A pharmacokinetic study was conducted in 2005 and later published in the Journal of Clinical Pharmacology comparing Evra to an oral contraceptive, which demonstrated that Evra was delivering higher serum concentrations of EE compared to an oral contraceptive with an EE dose of 35 micrograms. A pharmacokinetic study evaluates how the body handles a given drug over time; these studies are conducted by measuring the amount of time it takes for the drug to be absorbed, distributed and eliminated throughout the body.

Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in a unique black box warning and bolded warning in the Evra labeling.

The FDA held a Joint Meeting of the Advisory Committees for Reproductive Health Drugs and Drug Safety and Risk Management on December 9, 2011. The Committees concluded that users of Evra have an increased risk of VTE compared to users of second generation contraceptives, such as those containing LNG. The Committees, through a vote, concluded that the benefits of Evra outweighed the risks, but that the current package insert did not adequately reflect the risk/benefit profile.

A subsequent change to the labeling for Evra was implemented in August 2012.

The Evra market share declined rapidly following the labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013.

In April 2014, the Evra label was revised to provide revised dosage form and strength information. However, this revision did not affect the unique black box warning and bolded warning in the Evra label.

The approval of a generic equivalent to Evra was announced by Mylan Pharmaceuticals Inc. in April 2014.

We have conducted pharmacokinetic studies of Twirla to demonstrate that it delivers a daily EE dose of approximately 30 micrograms, comparable to a low-dose oral contraceptive. However, because none of our completed or planned clinical trials studied or expect to study Twirla in a head-to-head comparison with Evra, if Twirla is approved by the FDA, we will not be able to make direct comparative claims regarding the safety and efficacy of Twirla as compared to Evra. While we expect Twirla, if approved, to have the same black box warning currently required for all

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CHCs, we cannot predict whether the FDA will require that we include information in the Twirla labeling or black box warning regarding the additional risks associated with the Evra patch. Assuming approval, if we are not able to convince physicians, patients and payors that Twirla delivers a low daily dose of EE, this may limit uptake and usage of Twirla and our revenue will be limited.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We would have significant competition with contraceptive products already in the marketplace, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Any new product that competes with a previously approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability or safety to be commercially successful. In addition, new products developed by others could emerge as competitors to Twirla, if approved. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. These companies include Merck & Co., Inc., or Merck, which markets Nuvaring®, Actavis plc, or Actavis, which markets several branded and generic contraceptives including Loestrin® 24 and LoLoestrin®, Teva Pharmaceutical Industries Ltd., or Teva, which markets several branded and generic contraceptives including Gianvi® and Quartette®, Bayer AG, or Bayer, which markets Beyaz® and Mirena®, Johnson & Johnson, which markets Ortho-Tri-Cyclen® Lo and Ortho Evra®, Pfizer Inc., which markets Alesse® and Mylan Inc. which markets Xulane , a generic version of Ortho Evra. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., and Amneal Pharmaceuticals LLC.

There are other contraceptive product candidates in development that, if approved, would potentially compete with Twirla. Specifically, Bayer has a contraceptive patch recently approved in the European Union, or E.U., a patch and oral contraceptive, each in Phase 3 clinical development in the United States. Other companies that have new contraceptive product candidates in various stages of development include Teva (oral contraceptive in Phase 3), Merck (oral contraceptive in Phase 3), Actavis (vaginal ring and oral contraceptive in Phase 2) and Antares Pharma, Inc. (transdermal gel contraceptive in Phase 2).

Sales of our products, if approved, may be adversely affected by the consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The network through which we will sell our products, if and when approved, has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large distributors control a significant share of the market. In 2012, three companies generated about 85% of all revenues from drug distribution in the United States, and in 2010, four chain pharmacy companies owned about 30% of all retail pharmacy outlets. Consolidation of drug wholesalers and retailers, as well

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as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize Twirla and may affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for Twirla, restrict or regulate post-approval activities and affect our ability to profitably sell Twirla.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will change, or what the impact of such changes on the potential marketing approval of Twirla, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional healthcare policy reforms. The ACA, among other things, increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs, extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, addressed new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are line extension products and expanded the 340B drug discount program (excluding orphan drugs) to other entities. Further, the ACA imposed a significant annual tax on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with regard to healthcare practitioners.

Of particular relevance to our business is the ACA requirement that all health plans, with limited exceptions, cover certain preventive services for women with no cost sharing, which means no deductible, no co-insurance and no co-payments by the patient. Contraceptive methods and counseling, including all FDA-approved contraceptive methods as prescribed, are included in the ACA mandate, and this has come to be known as the "contraceptive mandate." Under the ACA, payors are only required to cover one favored product within each contraceptive "method" without imposing any cost-sharing obligations on the patient. For example, the introduction of a generic contraceptive patch product with a price that will likely be lower than the price of Twirla makes it less clear that Twirla would have a preferred position, such as coverage without a co-insurance payment, under the ACA contraceptive mandate. Other products within the same method may also be covered, but payors are allowed to use reasonable medical management techniques, such as the application of cost-sharing obligations. An amendment was issued that provided an exemption to the contraceptive mandate for group health plans established or

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maintained by religious employers. However, the contraceptive mandate has remained controversial, and several legal challenges have been filed around the country, including challenges pending in the U.S. Supreme Court. Although it is too early to determine the full effect of the contraceptive mandate and other provisions of the ACA on our business, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of our product candidates and reduce our profitability.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations related to product tracking and tracingon manufacturers of pharmaceutical products. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug products they produce to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' drug products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Third party coverage and reimbursement and healthcare cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market Twirla and other product candidates, if approved, will depend in part on the level of coverage and reimbursement that government authorities, private health insurers and other organizations provide for Twirla or our other product candidates and contraceptives in general. Countries in which Twirla or our other product candidates are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States,

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government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell Twirla or our other product candidates profitably if adequate prices are not approved or coverage and reimbursement are unavailable or limited in scope. Increasingly, third party payors attempt to contain healthcare costs in ways that are likely to impact our development of products including:

- Failing to approve or challenging the prices charged for healthcare products;
- Introducing reimportation schemes from lower-priced jurisdictions;
- Limiting both coverage and the amount of reimbursement for new therapeutic products;
- Denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third party payors; and
- Refusing to provide coverage when an approved product is used for off-label indications.

Risks Related to Manufacturing and Our Reliance on Third Parties

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

We rely on Corium International, Inc., or Corium, our third party manufacturer, to produce clinical supplies of Twirla and our other product candidates, and we plan to continue relying on them for commercial supplies and samples of our product candidates, if approved. We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We lack the resources and the capabilities to manufacture Twirla or any of our product candidates on a clinical or commercial scale. The facilities used by Corium to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after submission of an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as Current Good Manufacturing Practices, or cGMPs, for manufacture of our product candidates and our products, if and when approved. If Corium or other contract manufacturers that we may use cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturer to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities that would also require FDA approval, and which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, if our contract manufacturer cannot successfully manufacture materials that conform to our specifications and the strict regulatory requirements of the FDA or others, we may be subject to other regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of product or investigational approvals, clinical holds or termination, disgorgement, restitution, exclusion from federal healthcare programs product seizures and detention, consent decrees corporate integrity agreements, criminal and civil penalties, including

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imprisonment refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution.

The machinery to produce the commercial supply of Twirla must be qualified and validated, which is time-consuming and expensive, and this machinery is located within one manufacturing site and is customized to the particular manufacturing specifications of Twirla. If Corium is unable to qualify and validate this equipment in a timely manner, our ability to launch and commercialize Twirla will be compromised. If this customized equipment malfunctions at any time during the production process, the time it may take Corium to secure replacement parts, to undertake repairs and to revalidate the equipment and process could limit our ability to meet the commercial demand for Twirla. Similar manufacturing conditions may also apply to our other product candidates. This may increase the risk that the third party manufacturer may not manufacture Twirla in accordance with the applicable regulatory requirements, that we may not have sufficient quantities of Twirla or our product candidates or that we may not have such quantities at an acceptable cost, any of which could delay, prevent, or impair the commercialization of Twirla, if approved, and the development of our product candidates.

Although we have manufacturing agreements with Corium for the clinical and commercial supply of Twirla, Corium and several of its suppliers of raw materials will be single source providers to us for a significant period of time. In particular, Corium manufactures Twirla using EE and LNG and components that it purchases from third parties, most of which are single source suppliers of the applicable material. We do not have any control over the process or timing of the acquisition of these raw materials by Corium. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Because we outsource all of our manufacturing processes, there is no guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Although Corium intends to enter into agreements with critical manufacturers, component fabricators and secondary service providers to secure commercial supply of Twirla, not all of such suppliers and service providers will be under contract. Any delays in obtaining adequate supplies of our product candidates could limit our ability to meet commercial demand for Twirla.

In addition, in the event Twirla is approved and achieves significant market share, Corium may not possess adequate manufacturing capabilities to meet market demand for Twirla. If it becomes necessary to engage an additional third party manufacturer to produce Twirla, we may need to license certain manufacturing know-how from Corium, or our commercial supply will be limited while the new third party manufacturer develops the necessary know-how to manufacture Twirla.

Reliance on a third party manufacturer subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including:

- Reliance on the third party for regulatory compliance and quality assurance;

- Reduced control over the manufacturing process for our product candidates;

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The possible breach of the manufacturing agreements by the third party because of factors beyond our control;

The possibility of termination or nonrenewal of the agreements by the third party because of our breach of the manufacturing agreement or based on their own business priorities; and

The disruption and costs associated with changing suppliers.

Our product candidates may compete with other products and product candidates for access to manufacturing resources and facilities. There are a limited number of manufacturers that operate under cGMP requirements and that are both capable of manufacturing for us and willing to do so. If our existing third party manufacturer, or the third parties that we may engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to manufacture our product candidates for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our third party manufacturer is subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. In addition to the above-described regulatory actions, failures by our third party manufacturer to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another third party manufacturer that meets all regulatory requirements.

We are dependent on numerous third parties in Corium's supply chain for the supply of our product candidates, and if Corium fails to maintain supply relationships with these third parties, develop new relationships with other third parties or suffers disruptions in supply, we may be unable to continue to develop our product candidates, or, assuming FDA approval, commercialize Twirla.

We, through our manufacturing partner Corium, rely on a number of third parties for the supply of active ingredients and other raw materials for the clinical supply of our product candidates and, assuming FDA approval, commercialization of Twirla. Our ability to develop our product candidates depends, in part, on Corium's ability to successfully obtain the active pharmaceutical ingredients used in our product candidates, in accordance with regulatory requirements and in sufficient quantities for clinical testing and later commercialization. If Corium fails to develop and maintain supply relationships with these third parties, we may be unable to continue to develop our product candidates or commercialize any approved products in the future.

We, through Corium, also rely on certain third parties as the current sole source of the materials they supply. Although many of these materials are produced in more than one location or are available from another supplier, if any of these materials becomes unavailable to us for any reason, we likely would incur added costs and delays in identifying or qualifying replacement materials and there can be no assurance that replacements would be available to us on acceptable terms, or at all. In certain cases we may be required to get regulatory approval to use alternative

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suppliers, and this process of approval could delay development of our product candidates and, assuming FDA approval, commercial production of Twirla, indefinitely.

If Corium's third party suppliers fail to deliver the required quantities of sub-components and starting materials, in accordance with all regulatory requirements, and on a timely basis and at commercially reasonable prices, and we and Corium are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued development of our product candidates, and assuming FDA approval, commercialization of Twirla, would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

If the manufacturing facilities of Corium are not maintained in a manner that is compliant with cGMP requirements, we may need to find alternative manufacturers and suppliers, which could result in supply interruptions of Twirla and our other product candidates, additional costs and lost revenues.

Corium's facilities used for the manufacture of our product candidates must be maintained in a manner compliant with cGMP requirements, including obtaining favorable inspection reports. We do not control the manufacturing process and are dependent on Corium for compliance with the FDA's requirements for manufacture of Twirla and our other product candidates. If Corium cannot successfully manufacture material components and finished products that conform to our specifications and the FDA's strict regulatory requirements, they and we may be subject to regulatory action, including adverse inspectional findings, Warning Letters, Untitled Letters, product recall requests, withdrawal of product or investigational approvals, clinical holds or termination, disgorgement, restitution, exclusion from federal healthcare programs detentions or seizures, refusal to allow the import or export of a product, injunction against or restriction of manufacture or distribution, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, and Corium may not be able to maintain FDA approval for its manufacturing facilities or acceptance of its manufacturing data in regulatory filings. If Corium's facilities cannot maintain compliance with FDA requirements, we may need to find and successfully qualify alternative manufacturing facilities, which could result in supply interruptions of Twirla and our other product candidates and substantial additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues.

We rely on third parties to conduct aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with applicable regulatory requirements, we may be delayed in obtaining or ultimately not be able to obtain marketing approval for our product candidates.

We currently rely on CROs for most aspects of our clinical trials, including trial conduct, data management, statistical analysis and electronic compilation of our NDA. We may enter into agreements with CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to new or ongoing clinical and preclinical programs. Entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and the time the CRO commences work. As a result, delays may occur, which may materially impact our

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ability to meet our desired clinical development timelines and ultimately have a material adverse impact on our operating results, financial condition or future prospects.

As CROs are not our employees, we cannot control whether or not they devote sufficient time and resources to our clinical trials for which they are engaged to perform, and whether they comply with the applicable regulatory requirements, known as Current Good Clinical Practices, or cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development, which include requirements related to the conduct of the study, subject informed consent, and IRB approval. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. Although we may rely on third parties for the execution of our trials, we are nevertheless responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, in addition to the additional Phase 3 clinical trial that we are planning to conduct in response to the CRL that we received from the FDA in February 2013. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product candidate materials produced under cGMP regulations. Our failure to comply with these regulations may require us to discontinue or repeat clinical trials, which would delay the regulatory approval process. If the CROs we engage do not successfully carry out their contractual duties or obligations, conduct the clinical trials in accordance with all regulatory requirements, or meet expected deadlines, or if they need to be replaced, or the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements or for other reasons, then our development programs may be extended, delayed or terminated, or we may not be able to obtain marketing approval for or successfully commercialize our product candidates. Failure to comply with clinical trial regulatory requirements may further subject us to regulatory action, including Warning Letters, Untitled Letters, adverse inspectional findings, clinical holds or termination, criminal and civil penalties, including imprisonment, injunction against manufacture or distribution and debarment. As a result, our financial results and the commercial prospects for our product candidates would be harmed and our costs would increase.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek partnerships, collaborations and other strategic transactions to maximize the commercial potential of Twirla, our other product candidates and our proprietary technologies in the United States and territories throughout the world. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for Twirla and each of our other product candidates and technologies, both in the United States and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to

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negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters could lead to delays in the development process or commercialization of our product candidates and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If we fail to establish an effective distribution process our business may be adversely affected.

We do not currently have the infrastructure necessary for distributing pharmaceutical products. We intend to contract with third party logistics wholesalers to warehouse these products and distribute them to pharmacies. This distribution network will require significant coordination with our sales and marketing and finance organizations. Failure to secure contracts with wholesalers could negatively impact the distribution of our products, if and when approved, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of our products, if and when approved, will be delayed or severely compromised and our results of operations may be harmed.

Risks Related to Regulatory Matters Following Approval

Even if we obtain marketing approval for Twirla or other product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Twirla or other product candidates could be subject to labeling and other restrictions, including withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Even if we obtain U.S. regulatory approval of Twirla or other product candidates, the FDA may still impose significant restrictions on their indicated uses, including more limited patient populations, require that precautions, contraindications, or warnings be included on the product labeling, including black box warnings, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Claims that we may make may also be restricted through our approved labeling. Twirla and our other product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping,

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reporting of adverse events and other post-market information, and further development. These requirements include registration with the FDA, listing of our drug products, payment of annual fees, as well as continued compliance with cGCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Should the inspectional findings not be resolved to the FDA's satisfaction or should the finding rise to a sufficient level, the FDA and other government authorities may issue a Warning Letter or Untitled Letter, or take other regulatory action such as a product seizure and detention, withdrawal of product approval, request for a recall, refusal to allow the import or export of the product, criminal or civil penalties, including imprisonment, injunction against or restriction of manufacture or distribution, consent decrees disgorgement, restitution, clinical holds or terminations, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the information that patients must be provided, distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry.

With respect to sales and marketing activities by us or any future collaborative partner, advertising and promotional materials must comply with the FDA's rules in addition to other applicable federal and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws, which impact, among other things, our proposed sales, marketing and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if Twirla and our other product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. If we receive marketing approval for Twirla or our other product candidates, physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and

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government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. For example, we believe that Twirla, if approved, will have a label consistent with all other marketed hormonal contraceptive products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clots, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease, and hypertension, and a black box warning regarding risks of smoking and CHC use, particularly in women over 35 years old that smoke. However, regulatory authorities may require the inclusion of additional statements about adverse events in the label, including additional black box warnings or contraindications.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines that are as much as $3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or a regulatory agency discover previously unknown problems with a product candidate, once approved, such as adverse events of unanticipated severity or frequency, data integrity issues with regulatory filings, problems with the facility where the product is manufactured or we or our manufacturers or others working on our behalf fail to comply with applicable regulatory requirements before or after marketing approval, we may be subject to reporting obligations as well as the following administrative or judicial sanctions:

- Restrictions on the marketing distribution or manufacturing of the product, withdrawal of the product from the market, or requests for product recalls;

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Issuance of Warning Letters, Cyber Letters or Untitled Letters;

Mandate modification to promotional materials and labeling or require us to provide corrective information to healthcare providers;

FDA or regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings and other safety information about the product;

Require us to enter into a consent decree or corporate integrity agreement, which can include imposition of various fines, reimbursement for inspection costs, required due dates for specific actions and penalties for noncompliance;

Clinical holds or termination;

Injunctions or the imposition of civil or criminal penalties, imprisonment, monetary fines disgorgement or restitution;

Suspension or withdrawal of regulatory approval;

Suspension of any ongoing clinical trials;

Refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

Debarment;

Exclusion from participation in federal healthcare programs or refusal of government contracts

Suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or

Product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Twirla or our other product candidates, if approved, and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Moreover, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if Twirla receives marketing approval by the FDA in the United States, we may never receive marketing approval for or commercialize Twirla or any other product candidates outside the United States.

In order to market Twirla or any other product candidate outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things,

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clinical trials and commercial sales, pricing and distribution of our product candidates. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with obtaining FDA approval in the United States, as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FDCA in the United States, which relates to the ability of an NDA applicant to use published data not developed by such applicant, may not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize our products, when and if approved, without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and efficacy dossiers. In addition, in many countries outside the United States, it is required that a product receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. Further, the product labeling requirements outside the United States may be different and inconsistent with the U.S. labeling and to the detriment to the product, and therefore negatively affect the ability to market in countries outside the United States.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

We have received conditional approval from the FDA for the use of Twirla as the proprietary name for our lead product candidate, AG200-15. However, this approval is conditional upon a further and final review by the FDA at the time of NDA approval. Additionally, any name we intend to use for our other product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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Our relationships with physicians, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any product candidates that we commercialize. Our arrangements with third-party payors, including government healthcare programs, and customers will expose us to broadly-applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Twirla, if approved, and any other product candidates we commercialize. Restrictions under applicable federal and state healthcare laws and regulations include the following:

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, impose obligations on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that create receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

The federal physician payment transparency requirements under the ACA and applicable regulations require manufacturers of drugs, devices, biologics and medical supplies to report certain information to the Department of Health and Human Services including information related to payments and other transfers of value made to physicians and teaching hospitals and the ownership and investment interests held by physicians and their immediate family members; and

Analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information

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related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the relevant government or regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes; such that a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations are costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities conducted by our sales team in the sale of Twirla or our other product candidates, if approved, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, corporate integrity agreements, refusal of government contracts, contract debarment and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Intellectual Property Rights

We may not be able to protect our proprietary technology in the marketplace.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee's ability to maintain our patents and to obtain additional patent protection in the United States and other countries with respect to our proprietary technology and products. We believe we will be able to obtain, through prosecution of our pending patent applications, additional patent protection for our proprietary technology. If we are compelled to spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer for sale the same or similar products containing the generically available active pharmaceutical ingredients in our product candidates, which could materially adversely affect our competitive business position and harm our business prospects. Our patents may be challenged,

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narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our product candidates. Even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Our product candidates contain generically available active pharmaceutical ingredients. As a result, composition-of-matter patents directed to the active pharmaceutical ingredients in our product candidates, which are generally believed to offer the strongest form of patent protection, are not available for our product candidates.

Patents that we own or may license in the future do not necessarily ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- The active pharmaceutical ingredients in our product candidates are generic and therefore our patents do not include claims directed solely to the active pharmaceutical ingredients;
- Our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates using the same active pharmaceutical ingredients;
- There can be no assurance that the term of a patent protection will be long enough for our company to realize sufficient economic value under the patents following commercialization of our product candidates;
- We do not expect, upon approval of our NDA, to receive patent term restoration under the Hatch-Waxman Act for the five patents that have been submitted to the FDA for listing in the Orange Book;
- Our issued patents and pending patent applications that may issue as patents in the future may not prevent entry into the U.S. market or other markets of generic versions of our Twirla and AG890 product candidates;
- We do not at this time own or control issued foreign patents in all markets that would prevent generic entry into some markets for our product candidates;
- We may be required to disclaim part of the term of one or more patents;
- There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;

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There may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;

There may be other patents issued to others that will affect our freedom to operate;

If our patents are challenged, a patent office or a court could determine that they are invalid or unenforceable;

There might be changes in the law that governs patentability, validity and infringement of our patents that adversely affects the scope or enforceability of our patent rights;

A court could determine that a competitor's technology or product that is the same as or similar to, our product candidates does not infringe our patents; and

Our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire or be held invalid or unenforceable before our company can realize sufficient economic value following commercialization of our product candidates.

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Our intellectual property portfolio is currently comprised of issued patents and pending patent applications. If our issued patents are found to be invalid, not enforceable or not infringed by competitor products, or pending patent applications fail to issue or fail to issue with a scope that is meaningful to our product candidates, our business will be adversely affected.

There can be no assurance that our pending patent applications will result in issued patents in the United States or foreign jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or enforceability, or that we will obtain sufficient claim scope or term in those patents to prevent a third party from competing successfully with our product candidates.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. To the extent that we have obtained or are able to obtain patents or other intellectual property rights in any foreign jurisdictions, it may be difficult for us to stop the infringement of our patents or the misappropriation of other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the availability of certain types of patent rights and enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and product candidates, and the enforcement of intellectual property.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. However, the full impact of the Leahy-Smith Act and the courts' review of any appeals to related proceedings, is in its early stages. Accordingly, the full impact that the Leahy-Smith Act will have on the operation of our business is not clear. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, as well as our ability to bring about timely favorable resolution of any disputes involving our patents and the patents of others.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in unenforceability, invalidity, abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in unenforceability, invalidity, abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or any future licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our products, when and if approved.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. There may be currently pending applications of which we are unaware that may later result in issued patents that our current or future product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our current or future product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or

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continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement or misappropriation. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our product candidates or their use, the holders of any of these patents may be able to block our ability to commercialize our product candidates unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product candidates or lead to prohibition of the manufacture or sale of product candidates by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or that claim ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any

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threatened or pending claims related to these matters or concerning agreements with our senior management, or other of our employees, consultants and contractors, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technological advances and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors, including the third parties we rely on to manufacture our product candidates, to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal to increase disclosure and make data more accessible to the public, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock.

We may be required to initiate litigation to enforce or defend our intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the

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resources available for development activities or any future sales, marketing or distribution activities.

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information and trade secrets could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, reissue, inter partes review, re-examination proceedings, third-party submissions of prior art, and other forms of post-grant review. In the United States, for example, post-grant review has recently been expanded. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

Risks Related to the Development of Our Additional Product Candidates

If we fail to develop and commercialize our current pipeline of additional product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited.

A key element of our strategy is to develop, obtain regulatory approval for and commercialize our portfolio of product candidates in addition to Twirla. To do so, we plan to utilize our

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proprietary transdermal delivery technology, Skinfusion, to develop additional product candidates. We may not be successful in our efforts to develop our portfolio of additional product candidates, and any product candidates we do develop may not produce commercially viable products that safely and effectively treat their indicated conditions. To date, our efforts have yielded three additional product candidates in addition to Twirla, 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.

Our development programs may initially show promise in identifying potential product leads, yet fail to produce product candidates for clinical development. In addition, identifying new treatment needs and product candidates requires substantial technical, financial and human resources on our part. If we are unable to obtain development partners or additional development program funding, or to continue to devote substantial technical and human resources to such programs, we may have to delay or abandon these programs. Any product candidate that we successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

We may be unable to license or acquire suitable additional product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products is competitive. A number of more established companies are also pursuing strategies to license or acquire products. These established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, we expect competition in acquiring product candidates to increase, which may lead to fewer suitable acquisition opportunities for us as well as higher acquisition prices.

Other factors that may prevent us from licensing or otherwise acquiring suitable product candidates include the following:

- We may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on our investment in such product;
- Companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us;
- We may be unable to identify suitable products or product candidates within our areas of expertise; or
- We may not have sufficient funds to acquire, develop or commercialize additional product candidates or technologies.

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Risks Related to Our Business Operations and Industry

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of April 15, 2014, we had a total of 11 full-time employees, and we use third-party consultants to assist with our current sales and marketing functions. As our development and commercialization plans and strategies develop, we expect to need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Twirla, if approved, and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided these employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. Competition for skilled personnel in our market is intense and competition for experienced personnel may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have an employment agreement with only one of our employees, Alfred Altomari, our President and Chief Executive Officer. The employment agreement provides for at-will employment, which means that Mr. Altomari or any of our other employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Mr. Altomari, or Dr. Elizabeth Garner, our Chief Medical Officer, may have a material adverse effect on our business. We do not currently carry "key person" insurance on the lives of members of executive management. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we

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have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Twirla or our other product candidates, if approved.

We face a potential risk of product liability as a result of the clinical testing of Twirla and our other product candidates and will face an even greater risk if we commercialize Twirla or our other product candidates, if approved or any other current or future product candidate. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of the product candidate subject to such claims. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

Decreased demand for Twirla or any future product candidates that we may develop;

Injury to our reputation;

Withdrawal of clinical trial participants;

Costs to defend any related litigation;

A diversion of management's time and our resources;

Substantial monetary awards to trial participants or patients;

Product recalls, withdrawals or labeling, marketing or promotional restrictions;

Loss of revenue;

The inability to commercialize Twirla or our other product candidates, if approved;

A decline in our stock price; and

Exposure to adverse publicity.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a $2.0 million annual aggregate coverage limit. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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We may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions and uncertainties, including those resulting from political instability and the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations, if necessary.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payors and distributors to purchase, pay for and effectively distribute our products if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future contract manufacturers, sole-source or single-source suppliers, or licensees to remain in business or otherwise manufacture or supply our product candidates. Failure by any of them to remain in business could affect our ability to manufacture product candidates.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage as we currently have. We estimate that we will annually incur approximately $2.0 million in expenses in response to these requirements.

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We also estimate that the expenses we will incur in completing this offering, not including the underwriting discount, will be approximately $ million.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the SEC. However, for as long as we remain an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible 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 SEC.

Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. We will incur substantial accounting expense and expend significant management efforts to comply with internal control over financial reporting requirements. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with these requirements in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Our headquarters are located in Princeton, New Jersey, and Corium, our contract manufacturer, is located in Grand Rapids, Michigan. We are vulnerable to natural disasters, such as severe storms and other events that could disrupt our or Corium's operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in

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a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and abroad and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We intend to adopt a code of conduct prior to completion of this offering, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including regulatory enforcement actions the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, corporate integrity agreements contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions contemplated by this offering.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in

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years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that the transactions described in this offering, either on a standalone basis or when combined with future transactions, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383.

Risks Related to this Offering and Ownership of Our Common Stock

An active trading market for our common stock may not develop and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we anticipate applying to list our common stock on NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

We expect that our stock price may fluctuate significantly.

Prior to this offering, you could not buy or sell our common stock publicly. An active public market for our common stock may not develop or be sustained after the completion of this offering. We will negotiate and determine the initial public offering price with the underwriters based on several factors. This price may vary from the market price of our common stock after this offering. You may be unable to sell your shares of common stock at or above the initial offering price. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- Any delay in filing our response to the CRL received from the FDA with respect to Twirla and any adverse development or perceived adverse development with respect to the FDA's review of our response;
- Adverse results in our planned Phase 3 clinical trial for Twirla;
- Our failure to commercialize Twirla, if approved, or develop and commercialize additional product candidates;
- Unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;

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Regulatory actions with respect to Twirla;

Inability to obtain adequate product supply of Twirla or inability to do so at acceptable prices;

Adverse results or delays in our clinical trials for our other product candidates;

Changes in laws or regulations applicable to Twirla or any future product candidates, including but not limited to clinical trial requirements for approvals;

Actual or anticipated fluctuations in our financial condition and operating results;

Actual or anticipated changes in our growth rate relative to our competitors;

Competition from existing products or new products that may emerge;

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

Failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

Issuance of new or updated research or reports by securities analysts;

Fluctuations in the valuation of companies perceived by investors to be comparable to us;

Share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

Additions or departures of key management or scientific personnel;

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

Announcement or expectation of additional debt or equity financing efforts;

Sales of our common stock by us, our insiders or our other stockholders; and

General economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may

otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the NASDAQ Global Market and the stock prices of pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

We may be subject to securities litigation, which is expensive and could divert management attention.

Our market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could

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adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our existing principal stockholders, executive officers and directors own a significant percentage of our common stock and will be able to exert a significant control over matters submitted to our stockholders for approval.

Prior to this offering, our executive officers, directors, director nominees, holders of 5% or more of our capital stock and their respective affiliates together beneficially owned approximately 91.9% of our voting stock and, upon consummation of this offering, that same group will together hold approximately % of our outstanding voting stock, assuming no exercise of the underwriters' over-allotment option, no exercise of outstanding options and after giving effect to the issuance of shares in this offering.

This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that other stockholders may feel are in their best interest and our large stockholders may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Future sales of shares of our common stock by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline significantly and could decline below the initial public offering price. Based on shares outstanding as of December 31, 2013, and including the effect of the conversion of our convertible preferred stock and the net exercise of outstanding warrants to purchase shares of convertible preferred stock into shares of our common stock, upon the completion of this offering, we will have outstanding shares of common stock, assuming no exercise of outstanding options. Of these shares, assuming no shares are purchased in this offering by our existing stockholders, shares of common stock, plus any shares sold pursuant to the underwriters' option to purchase additional shares, will be immediately freely tradable, without restriction, in the public market. Our underwriters may, in their sole discretion, permit our officers, directors, employees and current stockholders to sell shares prior to the expiration of the lock-up agreements. Moreover, a relatively small number of our stockholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

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After the lock-up agreements pertaining to this offering expire and based on shares outstanding as of December 31, 2013 and including the effect of the conversion of our convertible preferred stock and the net exercise of outstanding warrants to purchase shares of convertible preferred stock into shares of our common 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, an additional shares will be eligible for sale in the public market. In addition, the shares subject to outstanding options under our stock option plans and the shares reserved for future issuance under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of this offering, holders of approximately million shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We will have broad discretion in how we use the proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the majority of the net proceeds from this offering to conduct a Phase 3 clinical trial for Twirla, obtain marketing approval and begin preparations for the U.S. commercial launch of Twirla, complete the equipment validation and expansion of Corium's manufacturing capabilities, develop our product pipeline, begin making principal and interest payments on our term loan with Oxford beginning in February 2015 and for working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, validation of capital equipment and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive

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as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible 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 SEC.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements allowed to us as an "emerging growth company" we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10-K for the year ending December 31, 2014, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over

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financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon consummation of this offering, we will become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We have never paid dividends on our common stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on our common stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

Investors in this offering will pay a higher price than the book value of our common stock.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. You will incur immediate and substantial dilution of $ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus. In

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the past, we issued restricted stock, options and warrants to acquire common stock at prices significantly below the assumed initial public offering price. To the extent any outstanding options or warrants are ultimately exercised, you will sustain further dilution.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon completion of this offering contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

Authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;

Provide for a classified board of directors, with each director serving a staggered three-year term;

Prohibit our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

Provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors;

Require advance written notice of stockholder proposals and director nominations; and

Require any action instituted against our officers or directors in connection with their service to the Company to be brought in the state of Delaware.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the Securities and Exchange Commission (including this registration statement), in press releases and in other communications to stockholders or the investment community, we may provide forward-looking statements concerning possible or anticipated future results of operations or business developments. These statements are based on our management's current expectations or predictions of future conditions, events or results based on various assumptions and our management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," and variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product candidate development, product candidate potential, regulatory environment, sales and marketing strategies, capital resources or operating performance. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this registration statement should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed in the "Risk Factors" included elsewhere in this registration statement. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date of this prospectus and except as required by law, we assume no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have been filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any issuance or sale of our common shares. Except as required by law, we do not assume any obligation to update any forward-looking statements.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of our common stock that we are offering will be approximately $ million, based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' overallotment option is exercised in full, we estimate that we will receive net proceeds of approximately $ million.

We intend to use approximately $31 million of the proceeds from this offering to fund an additional Phase 3 clinical trial for Twirla, our lead product candidate.

We intend to use the remainder of the proceeds as follows:

- approximately $4 to $6 million for the completion of the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities;
- approximately $2 to $4 million for the development of our product candidate pipeline, including Twirla line extensions; and
- the remainder of the net proceeds for making scheduled principal and interest payments beginning in February 2015 on our outstanding term loan with Oxford Finance, LLC and for working capital and general corporate purposes. For additional information related to this outstanding loan, including the interest rate and maturity, see "*Management Discussion and Analysis December 2012 Loan Agreement*".

As of the date of this prospectus, we cannot specify with certainty all of the particular uses of the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the implementation of our manufacturing strategy, the status of our product candidate development efforts, our sales and marketing activities, the amount of cash generated or used by our operations, and competition. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment-grade, interest-bearing securities. We cannot predict whether these investments will yield a favorable return.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by

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these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our capital stock since our inception. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, we anticipate that only appreciation of the price of our common stock, if any, will provide a return to investors in this offering for at least the foreseeable future.

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CAPITALIZATION

The following table describes our capitalization as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering, into an aggregate of shares of our common stock, (ii) the net exercise immediately prior to the closing of this offering of warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock that will subsequently be automatically converted into shares of common 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 (iii) the automatic conversion of all outstanding warrants to purchase shares of Series C convertible preferred stock into warrants to purchase 25,002 shares of common stock; and
- on a pro forma as adjusted basis to also reflect the sale of shares of common stock by us in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus.

You should read this capitalization table together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this prospectus.

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	As of December 31, 2013		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(1)(2)
		(In thousands) (Unaudited)	
Convertible preferred stock, par value $0.0001 per share:			
Series A-1, 284,743 shares authorized, 137,787 shares issued and outstanding, actual; none authorized, issued or outstanding, pro forma and pro forma as adjusted	$ 898	$	$
Series A-2, 99,178 shares authorized, 66,116 shares issued and outstanding, actual; none authorized, issued or outstanding, pro forma and pro forma as adjusted	544		
Series B, 4,510,066 shares authorized, 4,510,066 shares issued and outstanding, actual; none authorized, issued or outstanding, pro forma and pro forma as adjusted	44,928		
Series C, 2,711,734 shares authorized, 1,578,400 shares issued and outstanding, actual; none authorized, issued or outstanding, pro forma and pro forma as adjusted	22,862		
Common stock, par value $0.0001 per share, 12,000,000 shares authorized, 78,086 shares issued and 73,954 shares outstanding, actual; shares authorized, shares issued and outstanding pro forma; and shares authorized, shares issued and outstanding pro forma as adjusted	1		
Additional paid-in capital	46,873		
Deficit accumulated during the development stage	(118,314)		
Total stockholders' (deficit) equity	(71,442)		
Total capitalization	$ (2,208)	$	$

(1) A $1.00 increase in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock ultimately issuable upon expected net exercise of the outstanding warrants to purchase shares of convertible preferred stock, which would subsequently be automatically converted into shares of common stock, by shares. A $1.00 decrease in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase the number of shares of our common stock ultimately issuable upon expected net exercise of the outstanding warrants to purchase shares of convertible preferred stock, which would subsequently be automatically converted into shares of common stock, by shares.

(2) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would

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increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization on a pro forma as adjusted basis by approximately $ 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.

The preceding table excludes:

831,158 of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 at a weighted average exercise price of $4.81 per share;

25,002 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2013 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 December 31, 2013.

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DILUTION

The historical net tangible book value of our common stock as of December 31, 2013 was $(71.6) million, or $(968.16) per share, based on the number of shares of common stock outstanding as of December 31, 2013. Historical net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the actual number of outstanding shares of our common stock. As of December 31, 2013, we had a pro forma net tangible book value of $ million or $ per share of common stock. Pro forma net tangible book value per share is equal to our total tangible assets less total liabilities, divided by the pro forma number of shares of our outstanding common stock, counting as outstanding the shares of common stock underlying all outstanding preferred stock, including the 1,578,400 shares of Series C convertible preferred stock, 4,510,066 shares of Series B convertible preferred stock, 137,787 shares of Series A-1 convertible preferred stock and 66,116 shares of Series A-2 convertible preferred stock issued as of December 31, 2013 and including shares of common stock underlying the shares of Series A-1 and A-2 convertible preferred stock issuable upon the net exercise of certain warrants to purchase shares of Series A-1 and 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 the prospectus. After giving effect to the issuance of shares of common stock offered hereby at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and our estimated offering expenses, our pro forma net tangible book value as adjusted as of December 31, 2013, will be approximately $, or approximately $ per pro forma share of common stock. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$
Historical net tangible book value per share	$ (968.16)	
Increase attributable to the conversion of the convertible preferred stock		
Pro forma net tangible book value per share before this offering		
Increase per share attributable to new investors		
Pro forma net tangible book value per share after this offering		
Dilution per share to new investors		$

Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. If any shares are issued in connection with outstanding options or the underwriters' over-allotment option, you will experience further dilution.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by $ million, the pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution in pro forma as adjusted net tangible book value to new investors in this offering by $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting

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discounts and commissions. We may also increase or decrease the number of shares we are offering. An increase of 1.0 million shares in the number of shares offered by us, together with a concurrent $1.00 increase in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, (a) would increase our pro forma as adjusted net tangible book value as of December 31, 2013 by approximately $ million and (b) would also increase the pro forma as adjusted net tangible book value per share after this offering and the dilution in net tangible book value per share to new investors by $ and $, respectively, after deducting estimated underwriting discounts and commissions. Conversely, a decrease of 1.0 million shares in the number of shares offered by us together with a concurrent $1.00 decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, (a) would decrease our pro forma as adjusted net tangible book value as of December 31, 2013 by approximately $ million and (b) would also decrease the pro forma as adjusted net tangible book value per share after this offering and the dilution in net tangible book value per share to new investors by $ and $, respectively, after deducting estimated underwriting discounts and commissions.

The following table summarizes, on a pro forma basis as of December 31, 2013, the difference between existing stockholders and the new investors with respect to the number of shares of common stock purchased, the total consideration paid and the average price per share paid. The table assumes that the initial public offering price will be $, which is the midpoint of the price range set forth on the cover page of this prospectus.

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percent %	Amount	Percent %	
Existing stockholders			$		$
New investors					
Total		100%	$	100%	$

The share data in the table above is based on shares outstanding as of December 31, 2013, counting as outstanding the shares of common stock underlying all outstanding preferred stock, including the 1,578,400 shares of Series C convertible preferred stock, 4,510,066 shares of Series B convertible preferred stock, 137,787 shares of Series A-1 convertible preferred stock and 66,116 shares of Series A-2 convertible preferred stock outstanding as of December 31, 2013, and excludes:

- 831,158 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 at a weighted average exercise price of $4.81 per share;
- 25,002 shares of common stock available upon the exercise of outstanding warrants as of December 31, 2013 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 December 31, 2013.

If the underwriters' over-allotment option is exercised in full, the shares held by existing stockholders will decrease to % of the total number of shares of common stock outstanding after this offering, and the number of shares held by new investors will increase to , or %, of the total number of shares of common stock outstanding after this offering.

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SELECTED 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, 2012 and 2013 from our audited financial statements, included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Years ended December 31,		Period from Inception (December 22, 1997) to December 31, 2013
	2012	2013	
	(In thousands, except share and per share data)		
Statement of operations data:			
Operating expenses:			
Research and development	$ 17,387	$ 9,154	$ 86,218
General and administrative	5,930	3,574	26,344
Total operating expenses	23,317	12,728	112,562
Loss from operations	(23,317)	(12,728)	(112,562)
Total other income (expense)	57	(1,592)	(265)
Loss before benefit for income taxes	(23,260)	(14,320)	(112,827)
Benefit from income taxes			673
Net loss	(23,260)	(14,320)	(112,154)
Beneficial conversion charge	(600)		(6,160)
Net loss available to common shareholders	$ (23,860)	$ (14,320)	$ (118,314)
Weighted average basic and diluted common shares outstanding	28,227	35,347	
Loss per common share basic and diluted	$ (845.29)	$ (405.14)	

	As of December 31,	
	2012	2013
	(In thousands)	
Balance sheet data:		
Cash and cash equivalents	$ 20,014	$ 2,120
Total assets	27,518	14,405
Total current liabilities	2,107	6,844
Long term debt, less current portion	14,787	9,770
Convertible preferred stock	69,233	69,233
Deficit accumulated during the development stage	(103,994)	(118,314)
Total shareholders' deficit	$ (58,608)	$ (71,442)

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in tabular format are presented in thousands, except per share data, or as otherwise indicated.

Overview

We are a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products for women. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. We have developed a 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. Our lead product candidate, Twirla, also known as AG200-15, is a once-weekly contraceptive patch currently in Phase 3 clinical development.

Since our inception in 1997, we have devoted substantial resources to developing Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $17.4 million and $9.2 million during the years ended December 31, 2012 and 2013, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to develop Twirla and advance our pipeline of product candidates. To date, we have funded our operations primarily through sales of convertible preferred stock and convertible promissory notes, and a term loan. From inception through December 31, 2013, we had received net proceeds of approximately $121.2 million from such equity and debt sales and such term loan. As of December 31, 2012 and December 31, 2013, respectively, we had $20.0 million and $2.1 million in cash and cash equivalents.

We are a development stage company and have not generated any revenue. We have never been profitable and, from inception through December 31, 2013, our losses from operations have been $112.6 million. Our net loss was $23.9 million and $14.3 million for the years ended December 31, 2012 and 2013, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, Twirla and any other product candidates we advance to clinical development. If we obtain regulatory approval for Twirla, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing and distribution functions.

Following the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our

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continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. In the future, we may generate revenue from product sales, license fees, milestone payments and royalties from the sale of products developed using our intellectual property. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Twirla and any product candidates that we may advance in the future. If we fail to complete the development of Twirla or any other product candidates we advance in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities. Research and development expenses consist primarily of costs incurred for the development of Twirla and other current and future product candidates, which include:

- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials and preclinical studies;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expenses;
- the cost of acquiring, developing and manufacturing clinical trial materials such as our product candidates;
- costs associated with research, development and regulatory activities; and
- facilities and other expenses such as insurance and supplies.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our third party vendors.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla. We expect to increase our research and development expenses for the foreseeable future as we initiate further clinical trials.

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To date, our research and development expenses have related primarily to the development of Twirla. For the years ended December 31, 2012 and 2013 our research and development expenses were approximately $17.4 million and $9.2 million, respectively. The following table summarizes our research and development expenses by functional area for the years ended December 31, 2012 and 2013.

	Year ended December 31,	
	2012	2013
	(In thousands)	
Clinical development	$ 2,337	$ 693
Regulatory	3,326	2,686
Personnel related	1,837	1,783
Manufacturing commercialization	7,496	2,290
Manufacturing	2,042	840
Stock-based compensation	349	862
Total research and development expenses	$ 17,387	$ 9,154

It is difficult to determine with any certainty the duration and completion costs of our currently planned or future clinical trials of Twirla and any of our other current and future product candidates we may advance, or if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs and professional fees for legal, patent review, consulting and accounting services. General and administrative expenses are expensed as incurred.

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For the years ended December 31, 2012 and 2013, our general and administrative expenses totaled approximately $5.9 million and $3.6 million, respectively. We anticipate that our general and administrative expenses will increase in the future with the continued research, development and potential commercialization of Twirla and any of our other product candidates, and as we operate as a public company. These increases will likely include increased legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations.

Additionally, if in the future we believe regulatory approval of Twirla or any of our other product candidates appears likely, we anticipate that we would begin preparations for commercial operations, which would result in an increase in payroll and other expenses, especially as relates to the sales and marketing of our product candidates.

Emerging Growth Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, warrant liabilities and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the

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actual costs. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued liability or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low in any particular period. Based on historical experience, actual results have not been materially different from our estimates.

Warrant Liability

We account for detachable warrants to purchase convertible preferred stock as liabilities, as they are freestanding derivative financial instruments. The warrants are recorded as liabilities at fair value, estimated using a Black-Scholes option pricing model, and are subject to re-adjustment at each balance sheet date, otherwise known as marked to market, with changes in the fair value of the warrants recorded in our statements of operations.

Beneficial Conversion

When we issue a debt security that is convertible into preferred stock at a discount from the fair value of the preferred stock at the date the debt or equity security counterparty is legally committed to purchase such a security, or the commitment date, a beneficial conversion charge is measured and recorded on the commitment date for the difference between the fair value of our common stock and the effective conversion price of the convertible debt or equity security. If the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the

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convertible debt or equity security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the convertible debt or equity security. The amount allocated to the beneficial conversion feature is presented as a discount or reduction to the related debt security or as an immediate charge to earnings available to common stockholders.

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award is recognized over the period during which services are provided in exchange for the award, generally the vesting period.

Described below is the methodology we have used in measuring stock-based compensation expense. For any stock option grants occurring after the consummation of this offering, stock option values will be determined based on the quoted market price of our common stock, at the time of grant.

We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, 718 "Accounting for Stock Based Compensation," which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Compensation expense is recognized, on a straight-line basis, over the vesting period of the award. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the price volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Many of these assumptions are highly subjective. Prior to the consummation of this offering, we were a privately-held company, and therefore, we utilized data from several peer companies to estimate expected stock price volatility. We utilized a dividend yield of zero based on the fact that we had never paid cash dividends and had no current intention to pay cash dividends. The risk-free interest rate used for each grant was based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

The following table summarizes the weighted average assumptions we used in our Black-Scholes calculations:

	Year ended December 31,	
	2012	**2013**
Risk-free interest rate	0.80%	1.73%
Expected dividend yield	0%	0%
Expected volatility	105.2%	104.8%
Expected term (years)	6.25	6.25

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We record stock-based compensation expense as a component of research and development expenses or general and administrative expenses. For the years ended December 31, 2012 and 2013 we allocated stock-based compensation as follows:

	Year ended December 31,	
	2012	2013
	(In thousands)	
Research and development	$ 349	$ 862
General and administrative	316	476
Total	$ 665	$ 1,338

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined contemporaneously by our board of directors based upon valuation information provided to them. All options to purchase shares of our common stock have been granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants based in part on input from an independent third-party valuation. We determined the fair value of our common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation,* or the AICPA Practice Guide. In addition, our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including external market conditions affecting the pharmaceutical industry, trends within the pharmaceutical industry, the prices at which we sold shares of our different series of preferred stock, the superior rights and preferences of each series of preferred stock relative to our common stock at the time of each grant, our results of operations and financial position, the status of our research and development efforts, our stage of development and business strategy, the lack of an active public market for our common and our preferred stock, and the likelihood of achieving a liquidity event such as an initial public offering or sale of our company in light of prevailing market conditions.

Key variables used in applying the option pricing method are as follows:

the prices of our convertible preferred stock sold to or exchanged between outside investors in arm's length transactions and the rights, liquidation preferences and privileges included in the convertible preferred stock as compared to those of our common stock;

volatility we estimated volatility based on comparison to volatility of publicly-traded comparable companies;

time to liquidity we estimated time to a liquidity event based on the forecasted time to reach significant clinical development or regulatory events for Twirla that we believed could lead to an initial public offering or other type of liquidation event for our stockholders;

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risk-free interest rate we determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a liquidation event for our stockholders; and

discounts for lack of marketability because we were a privately held company at the time of the valuations, shares of our common stock were illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately-held business valuations, fundamental business factors and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model.

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. The per share estimated fair value of common stock in the table below represents the determination by our board of directors of the fair value of our common stock as of the date of grant, taking into consideration the various objective and subjective factors described above, including the conclusions, if applicable, of contemporaneous valuations of our common stock as discussed below. The following table presents the grant dates, number of underlying shares and related exercise prices of stock options granted between January 1, 2012 and December 31, 2013, along with the fair value per share used to calculate stock-based compensation expense pursuant to our 2008 Equity Incentive Plan:

Date of grant	Number of shares underlying option grants	Exercise price per option	Per share estimated fair value of option
December 6, 2012	494,611	$ 6.13	$ 5.00
October 1, 2013	19,667	$ 6.13	$ 5.04

For the valuation of stock options granted on the dates noted above, we used a combination of the Option Pricing Model, or OPM, and of the probability-weighted expected return method, or PWERM, which we refer to as the hybrid method. The OPM treats the rights of the holders of preferred and common shares as equivalent to that of call options on any value of the enterprise above certain break points of the value based upon the liquidation preferences of the holders of preferred shares, as well as their rights to participation and conversion. The value of the common stock can be determined by estimating the value of its portion of each of these call rights. Under the PWERM, the value of a company's common stock is estimated based upon an analysis of value for the company assuming a merger or sale as the only possible future event. The per share value of the common stock is based upon the probability-weighted present value of expected future equity values, under each of the possible future event scenarios, as well as the rights and preferences of each share class.

The OPM method sets the implied price of the most recent round of preferred stock to its original issuance price, and then calculates our implied equity value. The implied equity value is then used to calculate the value per common share. The values derived from the OPM method

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are then used to determine an initial estimated equity value. We then used an option-pricing model to allocate the calculated equity value between the shares of preferred stock and common stock outstanding, including estimated liquidation payments to the preferred stockholders for all series of preferred stock. A discount was then applied to reach the final valuation of the common stock based on the fact that, inasmuch as we were a private company, there were impediments to liquidity, including lack of publicly available information and the lack of a trading market. The discount was determined after considering a number of empirical studies related to discounts for lack of marketability and by using a protective put option model that considered such variables as an estimated time to liquidity of 1.5 years, estimated volatility of 72.0%, expected dividend yield of 0% of the underlying stock and a risk-free rate of 0.2%. In addition, the current restrictions on the marketability of our common stock were considered. We estimated a 30.0% discount for the lack of marketability.

In order to estimate the investment return for the merger or sale scenario, a range of future equity values is estimated over a range of possible event dates, all plus or minus a standard deviation for value and timing. The rights and preferences of each shareholder class are considered in order to determine the appropriate allocation of value to common shares. The value of each common share is then multiplied by a discount factor derived from the calculated discount rate and the expected timing of the merger or sale. A risk-adjusted discount rate is applied, as the probability weightings in the PWERM address the success rates of each scenario. The value per common share, taking into account sensitivities to the timing of the merger or sale, is then multiplied by an estimated probability for the merger or sale. A probability-weighted value per share of common stock is then determined.

For the stock option grants noted above, we estimated the fair value of our common stock by assigning an 65.0% weighting to the estimated fair value using the OPM back-solve method and a 35.0% weighting to the estimated fair value under the merger or sale scenario. We believe that the 65.0% weighting on the OPM back-solve method is appropriate due to the proximity of the issuance of our Series C preferred stock in July 2012 to the valuation date and the fact that the issuance included and was led by a new investor. The 35.0% weighting for the merger or sale scenario was deemed appropriate because at the time of the valuation, we believed that there was the possibility of a sale or merger following the then-anticipated approval of Twirla.

There is inherent uncertainty in our forecasts and projections and, if we had made different assumptions and estimates than those described previously, the amount of our stock-based compensation expense, net loss and net loss per share amounts could have been materially different.

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Results of Operations

Comparison of Years Ended December 31, 2012 and 2013

	Year ended December 31,		
	2012	2013	Change
	(In thousands)		
Operating expenses:			
Research and development	$ 17,387	$ 9,154	$ (8,233)
General and administrative	5,930	3,574	(2,356)
Total operating expenses	23,317	12,728	(10,589)
Other income (expenses)			
Interest expense	(140)	(1,513)	1,373
Interest income	26	2	(24)
Change in fair value of warrants	171	(81)	(252)
Loss before income taxes	(23,260)	(14,320)	(8,940)
Income tax provision (benefit)			
Net loss	(23,260)	(14,320)	(8,940)
Deemed dividend / beneficial conversion	(600)		600
Net loss attributable to common stockholders	$ (23,860)	$ (14,320)	$ (9,540)

Research and development expenses Research and development expenses decreased by $8.2 million, or 47%, from $17.4 million for the year ended December 31, 2012 to $9.2 million for the year ended December 31, 2013. This decrease in research and development expense was primarily due to the following:

a decrease in manufacturing related commercialization expenses of $5.2 million. During 2012, we paid our contract manufacturer $3.5 million toward the renovation of a dedicated facility for the manufacture of Twirla, and there were no comparable payments in 2013. In addition, payments for labor and materials decreased from approximately $3.9 million in 2012 to approximately $1.5 million in 2013, as the renovation of the facility was completed during 2013 and equipment was delivered during 2013. These decreases were partially offset by an increase in idle and other facility charges of $0.7 million;

a decrease in clinical development expenses of $1.6 million primarily related to the completion of our Phase 3 clinical trials of Twirla in early 2012. No clinical trials for Twirla or any of our other product candidates were conducted in 2013;

a decrease in manufacturing related costs of $1.2 million reflecting primarily a decrease in consulting costs associated with the filing of our New Drug Application, or NDA, as well as decreased material and labor costs;

a decrease in regulatory expenses of $0.6 million. The regulatory expenses for 2012 include consulting and NDA preparation fees as well as our Prescription Drug User Fee Act, or PDUFA, filing fee of approximately $1.8 million. Regulatory expenses for 2013 reflect the

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decrease in NDA preparation consulting and filing fees, offset, in part, by increased legal fees associated with preparing a response to the CRL we received from the FDA; and

these decreases were offset in part by an increase in stock-based compensation expense of $0.5 million as a result of the increased fair value of non-employee stock options.

General and administrative expenses General and administrative expenses decreased by $2.4 million, or 40%, from $5.9 million for the year ended December 31, 2012, to $3.6 million for the year ended December 31, 2013. This decrease was attributable to a decrease in commercial development costs of $1.4 million and a decrease in professional fees of $1.1 million. The decrease in commercial development expenses was primarily attributable to market research studies conducted in 2012 for which no comparable studies were conducted in 2013. The decrease in professional fees was related to our overall effort to reduce spending for legal, consulting and other professional fees.

Interest expense Interest expense is primarily attributable to our term loan with Oxford Finance LLC, or Oxford. Interest expense also includes the accretion of the value of the Series C preferred stock warrants issued to Oxford and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $1.4 million, or 980%, from $140,000 for the year ended December 31, 2012 to $1.5 million for the year ended December 31, 2013. The increase is due to our payment of a full year of interest associated with the term loan with Oxford in 2013, compared to our payment of only less than one month of interest expense in 2012.

Interest income Interest income is comprised of interest income earned on cash and cash equivalents.

Change in fair value of warrants Certain of the warrants to purchase our preferred stock are recorded at fair value and are subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding change recorded within the change in fair value of warrant liability. The fair value of the convertible preferred stock warrants is determined using the Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the underlying stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, credit spread and expected volatility of the price of the underlying stock. During the year ended December 31, 2013, the fair value of our derivative liabilities changed by $0.2 million as a result of the value of our preferred stock warrant derivative liabilities increasing primarily due to the change in fair value of the underlying stock.

Net Operating Losses and Tax Carryforwards

As of December 31, 2013, we had approximately $108.4 million of federal and $84.0 million of state net operating loss carryforwards. We also potentially have federal and state research and development tax credits which would offset future taxable income. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards

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for federal and state tax purposes. As of December 31, 2013, all of our net operating losses were fully offset by a valuation allowance.

Liquidity and Capital Resources

We have funded our operations since inception through the issuance of convertible preferred stock and convertible promissory notes and, to a lesser extent, through a term loan and government grants. As of December 31, 2013, we had raised a total of $121.2 million from such sales of our equity securities and debt instruments, as well as our term loan.

At December 31, 2013, we had cash and cash equivalents totaling $2.1 million. We invest our cash equivalents in highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2012 and 2013:

	Year ended December 31,	
	2012	2013
	(In thousands)	
Cash used in operating activities	$ (22,968)	$ (13,019)
Cash used in investing activities	$ (6,693)	$ (4,945)
Cash provided by financing activities	$ 40,113	$ 70
Net increase (decrease) in cash and cash equivalents	$ 10,452	$ (17,894)

Operating Activities

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our primary product candidate Twirla was being developed. With the planned initiation of an additional Phase 3 clinical trial in 2014, clinical development expenses are expected to increase as compared to 2013. Net cash used in operating activities was $23.0 million for the year ended December 31, 2012 and consisted primarily of a net loss of $23.3 million which was offset, in part, by non-cash stock based compensation expense of $0.7 million. Net cash used in operating activities was $13.0 million for the year ended December 31, 2013 and consisted primarily of a net loss of $14.3 million which was offset, in part, by non-cash stock based compensation expense of $1.3 million.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2012 and 2013 was $6.7 million and $4.9 million, respectively. Cash used in investing activities represents the acquisition of equipment to be used in the commercialization of Twirla.

Financing Activities

Net cash provided by financing activities was $40.1 million for the year ended December 31, 2012 which included (i) net proceeds of $22.9 million from the issuance of 1,578,400 shares of our Series C preferred stock, (ii) net proceeds of $14.8 million from a term loan and (iii) net proceeds

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of $2.5 million from the issuance of 253,999 shares of our Series B preferred stock. Net cash provided by financing activities was $70,000 for the year ended December 31, 2013 resulting from the exercise of stock options.

Funding Requirements and Other Liquidity Matters

Twirla is still in clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for Twirla;
- establish a sales and marketing infrastructure to commercialize Twirla in the United States, if approved;
- seek to identify additional line extensions for Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditures requirements through the first quarter of 2016. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of Twirla, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of Twirla, including for the additional Phase 3 trial for Twirla;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Twirla, if approved;
- the revenue, if any, received from commercial sales of Twirla, if approved; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to

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our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market Twirla that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2013 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Term loan	$ 17,638	$ 6,293	$ 11,345		
Operating lease	308	159	149		
Total	$ 17,946	$ 6,452	$ 11,494		

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. This lease expires in November 2015, however, we have the option to extend the term of the lease for an additional three years.

Legal Proceedings

In the ordinary course of business, we may be subject from time to time to various proceedings, lawsuits, disputes or claims. We do not believe there are currently any such actions that, if resolved unfavorably, would have a material impact on our financial condition, results of operations or cash flows.

December 2012 Loan Agreement

In December 2012, we entered into a loan and security agreement with Oxford, pursuant to which we borrowed a total of $15.0 million from Oxford. The term loan accrues interest at a fixed annual rate equal to 9.2% (three month U.S. Libor rate of 0.47% plus 8.73%).

Under the terms of the original term loan, interest was payable monthly and principal was due in 30 equal consecutive monthly installments which were to begin on February 1, 2014 and end on July 1, 2016. In addition, we were required to make a final payment of $675,000 on the original maturity date of the term loan of July 1, 2016.

We may prepay all, but not less than all, of the term loan subject to a prepayment premium of 2.0% of the outstanding principal during the first 24 months of the term loan. From months 25 to loan maturity the prepayment premium is 0.75% of the outstanding principal. Our obligations under the term loan are secured with a blanket lien on all of our assets, excluding intellectual property assets. The term loan provides that, upon the occurrence of certain events of default, our obligations under the term loan may be automatically accelerated, whereupon our obligations shall be immediately due and payable.

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In connection with the term loan, we issued to Oxford warrants to purchase 25,002 shares of Series C preferred stock at $15.00 per share. These warrants are exercisable for seven years from the date of issuance.

We account for the warrants as a liability and carry them at fair value. These warrants are marked to market at each reporting date with a corresponding change recognized in our statements of operations.

In January 2014, we amended our loan agreement with Oxford whereby the interest-only period was extended for three months through April 2014. The interest-only period may be extended for an additional three months through July 2014 should we receive cash proceeds of not less than $3.0 million from the sale of unsecured subordinated convertible debt or equity securities before May 1, 2014.

The interest-only period may be further extended for an additional six months through January 2015 should we receive cash proceeds of not less than $45.0 million from the sale of equity securities in a private placement or an initial public offering before August 1, 2014.

The maturity date of the loan will also be extended, to July 1, 2017, if we complete the sale of equity securities of not less than $45.0 million in a private placement or an initial public offering before August 1, 2014.

In connection with the amendment to the loan agreement we have agreed to pay Oxford a total of $150,000, of which $75,000 is due upon the closing of certain qualified financings and the remaining $75,000 is due upon the earlier of an initial public offering or loan maturity.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of $20.0 million and $2.1 million at December 31, 2012 and 2013, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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BUSINESS

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. We have developed a 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. Our lead product candidate, Twirla, also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. 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. Currently, there is only one other contraceptive patch available in the United States which is available in branded and generic versions, and we believe it has limitations due to its dose and physical characteristics. Twirla is designed to address these limitations. We believe there is an unmet market need for a low-dose contraceptive patch, which is designed to increase patient convenience and compliance in a non-invasive fashion.

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 hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives. Twirla is designed using our proprietary Skinfusion technology 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 patch is applied once weekly for three weeks, followed by a week without a patch. If approved, Twirla will be packaged with three patches per carton to provide for one 28-day cycle of therapy.

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.

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. After multiple communications with the FDA, we have received significant guidance as to what additional clinical development and other activities need to be completed

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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. Following completion of this additional Phase 3 clinical trial, we will respond to the CRL and supplement our NDA with the results of the trial.

We intend to commercialize Twirla in the United States, if approved, through a direct sales force. 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 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.

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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.

Background

Hormonal Contraception Overview

A woman is biologically capable of pregnancy from the time of her first menstrual cycle, at the average age of 12.6 years, to natural menopause, at the average age of 51.3 years. This is nearly half of a typical woman's lifespan and, for the typical woman, the majority of this time frame is spent trying to avoid pregnancy or is characterized by no desire to become pregnant. Nearly half of the pregnancies that occur each year in the United States are unplanned. The United States was the first country to approve a hormonal contraceptive, with the approval of the first contraceptive pill in 1960. The latest data from 2006 to 2008 from the Centers for Disease Control, or CDC, indicate that approximately 25% of women aged 15 to 44 use some form of hormonal contraception, which amounts to approximately 15 million U.S. women.

Hormonal contraceptives are composed of synthetic estrogens and progestins. Contraceptives containing both estrogen and a progestin are referred to as CHCs, and contraceptives containing only progestin are referred to as P-only. There are three synthetic estrogens approved for use in contraceptive products: EE, mestranol and estradiol valerate. EE has been available for over 40 years and is the estrogen component in nearly all CHCs today. There are 10 different progestins that have been used in contraceptives sold in the United States. The progestin component provides most of the contraceptive effect, while the estrogen component primarily provides cycle control, for example, minimizing bleeding or spotting between cycles. The progestin exerts its contraceptive effect by inhibiting ovulation, or release of an egg from the ovary, and by thickening cervical mucus. Thickening cervical mucus helps to prevent sperm entry into the upper genital tract. The estrogen component, in addition to providing cycle control, makes a small contribution to contraception by decreasing the maturation of the egg in the ovary.

Hormonal contraceptives are generally well-tolerated and are generally safer than pregnancy. A risk associated with hormonal contraceptives is a rare but serious adverse event called venous thromboembolism, or VTE, which involves the formation of a blood clot in a vein. VTEs can be life-threatening, and typically present as either deep vein thrombosis or pulmonary embolism. Evidence supports that the increased risk of VTE in CHC users is dependent upon the estrogen dose and duration of use. Estrogen increases formation of clotting factors in the liver and decreases production of elements that promote breakdown of blood clots. Most experts believe that progestins on their own have minimal to no impact on the clotting system, but some progestins, when combined with estrogen, can increase estrogen's effect on the clotting system. The likelihood of a woman spontaneously developing a VTE is extremely low and the use of combination oral contraceptives, or COCs, increases the incidence only slightly, and less than pregnancy. For example, the incidence of VTE in a non-pregnant woman who does not use a COC ranges from 1 to 5 cases per 10,000 woman-years, or WY. Among COC users, the incidence ranges from 3 to 12 cases per 10,000 WY. One WY is one woman using a contraceptive for one year, which is either 12 months or 13 cycles. However, in pregnancy the incidence of VTE

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increases to 5 to 20 cases per 10,000 WY and in the 12 weeks following delivery the incidence ranges from 40 to 65 cases per 10,000 WY.

The available progestins are commonly categorized into generations, based on their history of introduction in the United States. The first and second generation progestins, including LNG, have been available in contraceptive formulations in the United States for over 25 years. The third and fourth generation progestins, for example desogestrel and drosperinone, respectively, were introduced to reduce androgenic side effects, such as oily skin and acne. Epidemiologic data suggest that CHCs containing third and fourth generation progestins are associated with an increased risk of VTE as compared to those containing the second generation progestin, LNG.

Effectiveness of Hormonal Contraceptives

For the purpose of FDA approval, contraceptive effectiveness is measured by a calculation called the Pearl Index, or PI. The PI is a measure of the rate of pregnancies over a specific period of time in a clinical trial, and is expressed as the number of pregnancies per 100 WY of use. Each cycle lasts 28 days, so there are approximately 13 cycles in one year. According to FDA guidance, the PI calculation includes all pregnancies, but only includes cycles where the woman indicates that she engaged in sexual activity and did not use backup contraception, such as a condom, and where she has completed a study diary. The PI values from clinical trials are affected by several factors, including differences in study design, increased sensitivity of early pregnancy tests, weight and body mass index, or BMI, of the study population, user experience and inconsistent or incorrect use of the contraceptive method.

The contraceptive failure rates in clinical trials are generally lower than those seen once a CHC is approved and in use by a broad population, referred to as typical use, without the close monitoring of a clinical trial setting. There is a large difference in pregnancy rates under conditions of perfect use, where the method is used following the directions exactly, and typical use. For example, for CHCs, including oral contraceptives, the vaginal ring and the transdermal patch, the percent of women experiencing an unintended pregnancy during the first year of use is 0.3% for perfect use and 9.0% for typical use.

U.S. Hormonal Contraceptive Market Background

Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Non-hormonal products available in the United States include the diaphragm, male condom and female condom. There are several categories of hormonal contraception products available in the United States, including:

- oral contraceptives;
- one vaginal ring;
- one transdermal patch;
- intrauterine contraceptive devices, or IUDs;
- subcutaneous implants; and
- injectables.

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The U.S. hormonal contraceptive market recorded annual sales in 2013 of $5.6 billion, according to IMS Health. The CHC portion of the market, consisting of pills, a transdermal patch and a vaginal ring, generates significantly greater prescription volume and sales compared to the P-only portion of the market, consisting of IUDs, injectables, implants, and P-only pills. In 2013, IMS Health reported total U.S. sales of $4.2 billion for the CHC market and $1.4 billion for the P-only market. Twirla is a CHC and, if approved, we believe it will compete primarily with products in the CHC market.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. Historically, the market growth was flat to declining as measured by prescription volume. However, recently the CHC market has seen prescription volume growth, with a 4.8% increase in 2013 compared to 2012. The average annual growth rate in dollar sales for the five years ended December 31, 2013 was 4.5% for the total hormonal contraceptive market and 2.4% for the CHC market. Market growth in gross sales is primarily due to price increases amongst branded products.

We believe there are two possible factors primarily affecting recent prescription volume growth in the contraceptive market. First, according to U.S. Census Bureau data and projections, the population of women aged 15 to 44 years has been growing at a rate of approximately 0.4% to 0.5% per year since 2011, increasing this population by 250,000 to 300,000 women per year.

Contraceptive Population
(total women aged 15-44 yrs)

Source:
U.S. Census Bureau, National projections released 2008 based on 2000 census data.

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Second, in 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or collectively, the ACA, was signed into law, which, among other things, requires all health plans, with limited exceptions, to cover certain preventive services for women with no cost sharing, which means no deductible, no co-insurance and no co-payments by the patient, effective August 1, 2012. These services include those set forth in the Guidelines for Women's Preventive Services, or HRSA Guidelines, and adopted by the U.S. Department of Health and Human Services Health Resources and Services Administration. Contraceptive methods and counseling, including all FDA approved contraceptive methods as prescribed, are included in the HRSA Guidelines. Since these new ACA provisions went into effect in August 2012, quarterly prescription volume growth for the CHC market has risen from negative growth year-on-year to positive growth between 4.0% and 5.0% for each of the six quarters following implementation.

CHC Market TRx Growth (%) vs. Prior Year

Source:
IMS National Prescription Audit, IMS Health

During the period following enactment of the ACA, from September 2012 through June 2013, only generic oral contraceptives showed positive growth; however, in the third and fourth quarters of 2013, both the vaginal ring and the transdermal patch also showed positive growth. As interpreted by the applicable governmental agencies, health plans are only required to cover one product for each contraceptive "method" without cost-sharing by the patient. For other products that fall within the same "method" that are not the preferred product, payors are allowed to use reasonable medical management techniques, such as applying cost-sharing obligations. We therefore cannot be sure that the growth in the CHC market is due entirely to the new coverage and ACA requirements, and it is too early to determine the full effect of the ACA on our business. Although CHC market growth in the United States may decline from current levels over

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time, we believe the CHC market will maintain a long-term positive annual growth rate in line with contraceptive population growth.

In spite of the availability of generic contraceptives for over 25 years, branded products have maintained a significant share of the CHC market, with 55% of dollar sales and 27% of prescriptions for the 12 months ended September 2013. Branded contraceptives in the CHC market have driven significant increases in the value of branded total prescriptions, or TRx. In the five years ended December 2013, the average annual price increase among the top branded products was 11.7%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the top branded products was $41.53 in 2006 and rose to $89.35 by the end of 2013. In addition, as of February 2014, eight branded product manufacturers already increased their pricing in 2014 by an average of 9.4%, and the average WAC per cycle for the top 13 branded manufacturers is $94.44. The non-oral forms of CHC, the transdermal patch and the vaginal ring, are currently priced at $110.22 and $91.69 per cycle, respectively. We cannot predict whether the manufacturers of branded products will continue to increase prices going forward, but we believe we will be able to set a WAC price for Twirla, if approved, that is comparable to other branded CHC products at the time of launch. Based on IMS Health data, we estimate that each percentage point of market share of CHC total prescriptions in the United States currently represents approximately $108 million of annual gross sales potential for Twirla, if approved.

Contraceptive Pills

Based on data from the CDC, of women who choose to use a hormonal contraceptive, approximately 72% use the contraceptive pill, implant or patch, the majority of which use the contraceptive pill. We believe that contraceptive pills are the most popular choice because:

- patients and physicians are familiar with pills;
- pills were the first to market and have been aggressively promoted for a long period of time;
- historically, pills have been a covered benefit with good reimbursement in private and public healthcare plans; and
- pills are a non-invasive option.

However, compliance remains a significant draw-back with pills. Published studies have shown that the average woman who uses oral contraceptives misses approximately two to four pills per month, which increases the potential for unintended pregnancies. We believe that a patch can offer greater convenience than a pill, as it does not require daily administration and, for certain women, could lead to greater compliance and ease of use.

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the contraceptive market, and achieved a 10% share of the CHC market by September 2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to

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include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in a black box warning and bolded warnings unique to the Evra label. The Evra market share declined rapidly following the labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013.

In April 2014, Mylan Inc. announced the launch of Xulane , a generic version of Evra. Generic pharmaceutical products are the chemical and therapeutic equivalents of the brand or a reference listed drug, or RLD. Generic drugs are bioequivalent to their reference brand name counterparts. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the RLD product containing the same active ingredient. Bioavailability is a measure of the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of action. Under pharmacy dispensing rules governed by state law, if an automatic generic substitute is introduced, the pharmacist may dispense either the prescribed product, or they may replace it with a generic or another brand without being required to inform the patient or healthcare professional. In addition, the FDA offers a 180-day exclusivity period for generic products in specific cases. During this period, the first generic applicants to submit a substantially complete Abbreviated New Drug Application containing a paragraph IV certification to a listed patent are protected from competition from other generic versions of the same drug for the 180 days. At this time, we do not know whether Xulane will be considered an automatic generic substitute or if it will receive the benefit of the 180-day exclusivity period.

The FDA has maintained, in spite of the wording in the labeling for Evra and its approved generic, that none of the epidemiologic studies to date provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. An advisory committee for the FDA stated that the benefits of Evra outweigh the risks. In its denial of a Citizen's Petition calling for the withdrawal of Evra, the FDA followed the committee's recommendations stating that the increased VTE risk does not warrant removal from the market, and that the labeling revisions to the Evra label provide an update and guidance on the interpretation of the epidemiologic data about the risk of VTE with Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, Evra generated $150 million in gross sales in 2013.

We believe that the rapid uptake and acceptance of Evra upon its introduction demonstrates that there is an unmet market need for a transdermal patch as a contraceptive option. Also, the epidemiologic data on VTE risk suggest that there is a need for a contraceptive patch that delivers both a low dose of EE similar to oral contraceptives and a first or second generation progestin.

Our Product Candidates

Each of our product candidates utilizes our proprietary Skinfusion technology, which is designed to provide advantages over the currently available patch. Skinfusion is designed to deliver contraceptive-levels of hormones to the blood stream through the skin over a seven-day period. It is also designed to optimize patch adherence and stability and patient comfort. Our lead product candidate is Twirla, a prescription CHC patch which contains both EE and LNG and is designed to deliver a low dose of EE and LNG comparable to the total dose delivered with low-dose oral

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contraceptives. 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 and AG200-SP, which is a regimen designed to provide a shortened hormone-free interval. We are also developing AG890, which is a P-only prescription contraceptive patch intended for use by women who are unable or unwilling to take estrogen.

Our current product candidate pipeline is summarized in the graphic below:

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Twirla Product Overview

Twirla is a CHC patch which contains both EE and LNG. Twirla is designed to address an unmet medical need for increased compliance and improved ease of use as compared to oral contraceptives. A single Twirla patch delivers the active ingredients LNG and EE over a seven-day dosing interval, and thereby eliminates the need to take a daily pill as is necessary with an oral contraceptive. Twirla uses a traditional 28-day contraceptive regimen, where one patch is applied weekly for three consecutive weeks and then there is a fourth patch-free week in each 28-day time period. Twirla may be applied to the buttock, abdomen or upper torso, but not the breast. In clinical trials to date, women most frequently chose the buttock and abdomen for patch placement. The exact patch location needs to be rotated with each patch change. Twirla has demonstrated a therapeutically equivalent pharmacokinetic profile when worn on the buttock, abdomen or upper torso. A drug's pharmacokinetic profile refers to the specific way in which a given drug is handled by the body over time, reflecting the particular patterns of absorption, distribution and elimination of the drug in the body.

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Twirla is designed to be highly appealing to patients as a method of contraception. The patch 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 that contain the active ingredients EE and LNG, as well as the inactive ingredients Dimethylsulfoxide, Ethyl Lactate, Capric Acid and Lauryl Lactate, which are ingredients to assist in the transport of EE and LNG across the skin, and adhesives that enable adherence to the skin. The final top layer is the one seen on the skin, and consists of a thin, silky material with adhesive only. 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 edge 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, 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.

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Twirla Patch Profile

The following table compares Twirla with the currently marketed Evra product as stated in its label, based upon publicly-available information regarding Evra and the characteristics of Twirla and other Twirla attributes observed in our Phase 3 clinical trials. We have not performed a head-to-head comparison of Twirla to Evra.

Characteristic	**Twirla**	**Ortho Evra***
Form of product	Transdermal patch Round, approximately 28 square centimeters Soft, silky, stretchy fabric	Transdermal patch Square, approximately 20 square centimeters Smooth, plastic film
Active ingredients	EE, LNG	EE, norelgestromin
Pharmorokinetic profile of EE per day	~30 micrograms	60% higher than that of an oral contraceptive containing 35 micrograms (~56 micrograms)**
Regimen	One patch weekly 21 days active / 7 days patch-free	Same as Twirla
Package configurations	1 box of 3 patches = 1 cycle 1 box with 1 patch = replacement	Same as Twirla
Top four adverse events/reactions in clinical trials	Nausea 3.0% Application site irritation 2.4% Breast tenderness 2.1% Headache 2.0%***	Breast symptoms 22.4% Headache 21.0% Application site disorders 17.1% Nausea 16.6%

*
Source of Ortho Evra data is U.S. prescribing information or package insert.

**
The Ortho Evra package insert indicates a strength of 35 micrograms of EE per day.

***
Adverse events deemed definitely, probably or possibly related to Twirla in completed Phase 3 clinical trials.

Twirla **Evra**

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Twirla employs our Skinfusion patch technology, resulting in a unique appearance and feel of the patch. Evra does not utilize our Skinfusion technology, its active ingredients and adhesives are dispersed to its edges. One frequent complaint about patches that do not utilize Skinfusion is that they collect dirt and lint and may leave a sticky black ring of residue on the skin which can be difficult to remove. We do not have any direct comparison of the appearance of the patch on the skin at the end of seven days between Twirla and Evra, but we believe, based on anecdotal feedback from our clinical trial investigators, as well as based upon the differences in the design of the two patches, that Twirla may have an advantage in this regard.

We have not performed a head-to-head comparison of Twirla to Evra, however, a pharmacokinetic study that we conducted with Twirla was similar in design to the pharmacokinetic study conducted with Evra that provided the information regarding the daily amount of EE delivered that is currently in the Evra package insert. The figure below combines the results for average EE concentrations from these two studies, and suggests a comparison of the observed blood concentration of EE for Twirla versus Evra versus observed and estimated data for the pill. The lower amount of EE delivered from Twirla as compared to Evra can be observed. If Twirla is approved by the FDA, we will not be able to make direct comparative claims regarding the safety, efficacy or pharmacokinetics of Twirla and Evra, since none of our completed clinical trials studied, nor does our contemplated additional Phase 3 clinical trial expect to study, Twirla in a head-to-head comparison with Evra.

EE Concentrations (pg/ml)

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The Evra curve presented in the graphic above was estimated based on the graph provided in the Evra label. In the legend to the figure above, "OC" refers to an oral contraceptive containing 35 micrograms of EE. The OC data prior to Day 21 are estimated steady-state data based on Day 21 EE concentrations observed during our pharmacokinetic study.

Twirla contains LNG, which is the progestin used as the reference standard when comparing risk of VTE between progestins. Evra contains the progestin norelgestromin, which is a prodrug of norgestimate, a second generation progestin that has not demonstrated an increased risk of VTE independent of EE. We do not expect any meaningful clinical differences between Twirla and Evra based on the progestin component, but our market research with ObGyns has demonstrated that they perceive LNG to be one of the safest progestins available.

Twirla Product Profile

Assuming completion of a successful additional Phase 3 clinical trial and approval of our marketing application by the FDA, we believe the clinical trial data from the planned Phase 3 trial for Twirla will support our future marketing of Twirla as follows:

- Twirla is a weekly contraceptive patch, designed to offer convenience and compliance.
- Twirla is designed to meet the contraceptive needs and the busy lifestyle of today's women.
- Twirla contains the active ingredients EE and LNG, both of which have been used in contraceptives for over 25 years.
- Twirla delivers the low daily dose of EE of approximately 30 micrograms, comparable to low-dose oral contraceptives.
- Twirla is designed to demonstrate efficacy comparable to other approved prescription contraceptives.
- Twirla has a favorable safety and tolerability profile.
- Twirla was designed with Skinfusion technology, which has demonstrated adhesion over the seven-day wear period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.
- Because Twirla contains the progestin LNG, we believe that the final approved label for Twirla will be consistent with the class labeling for other contraceptives containing EE and LNG, including the class black box warning.

Twirla Clinical Development Program

Completed Clinical Trials

We have conducted a clinical program that includes three Phase 1 studies, one Phase 2 study, and two Phase 3 studies, as well as other supporting studies. We are also planning a third Phase 3 study in response to FDA comments and guidance, which we anticipate initiating in the third quarter of 2014. 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 currently marketed low-dose oral contraceptives. In our completed Phase 3 clinical trials, we demonstrated that Twirla was comparable to an approved low-dose oral contraceptive in two randomized studies, one that

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enrolled over 1,500 women over 12 months and the other that enrolled over 400 women over six months. Across all clinical trials, Twirla was generally well-tolerated and had a favorable safety profile. Because we relied, in part, on the FDA's findings of safety and efficacy from investigations for approved products containing EE and LNG and published scientific literature for which we have not obtained a right of reference, we were not required to conduct preclinical studies. In the pharmacokinetic study comparing Twirla to an approved low-dose oral contraceptive, results demonstrated that Twirla delivers a daily dose of EE that results in estrogen exposure similar to low-dose oral contraceptives containing approximately 30 micrograms.

Our two completed Phase 3 trials enrolled over 1,900 subjects to evaluate the safety and efficacy of Twirla. Each of these studies included an active comparator arm with an approved low-dose oral contraceptive. The results of these studies demonstrated that Twirla was generally well-tolerated, with levels of adverse events generally comparable to those of low-dose oral contraceptives. In these studies, subjects had a higher rate of compliance when using the patch as compared with the group using oral contraceptives. However, as discussed further below, the FDA issued a CRL in response to our marketing application for Twirla and requested an additional Phase 3 study and additional chemistry manufacturing and control, or CMC, information. The results of the larger of our Phase 3 clinical trials demonstrated that approximately only 3% of patches became completely detached from the skin of subjects during the seven-day period, and that the patch generally remained adhered to the skin even when exposed to normal daily activities and conditions such as showering, swimming and other forms of exercise, heat and humidity.

More specifically, our safety population included subjects who received at least one dose of Twirla or COC. In the combined safety population of our completed Phase 3 trials, there were a total of 22 serious adverse events, or SAEs, of which 16 were from the Twirla cohort, which had approximately 2.3 times as many subjects as the oral contraceptive comparator cohort. Three of these SAEs (0.2% of the overall Twirla safety population) were considered to be possibly related to the study drug and included one drug overdose with Benadryl®, one case of uncontrollable nausea and vomiting and one instance of deep vein thrombosis. In addition to the SAEs described above, some subjects taking Twirla experienced non-serious adverse events, such as nausea, headache, application site irritation and breast tenderness. Subjects receiving the oral contraceptive comparator also generally experienced similar non-serious adverse events such as nausea, headache, and breast tenderness, though at different rates. We believe that Twirla will have a label consistent with all marketed low-dose CHC products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clots, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease and hypertension, and a black box warning regarding risks of smoking and CHC use and particularly in women over 35 years old that smoke.

In our Phase 3 trials, the primary measure of efficacy is the PI, which is calculated based on the number of observed on-treatment pregnancies and total number of on-treatment cycles during the study. Specifically, the PI is expressed as the number of pregnancies per 100 WY of use. The pooled PI value in the completed Phase 3 trials for the Twirla patch was 5.76 and for the combined oral contraceptive control arms was 6.72, which were higher than the range of 1.34 to 3.19 in pivotal studies conducted on products approved by the FDA in the previous ten years.

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We believe that the results for both the patch and oral contraceptive control arms in the Phase 3 trials were affected primarily by issues with study conduct at several study sites, including rapid enrollment which led to inability to manage the study population, poor subject compliance, and high rates of loss to follow-up. In the larger of our Phase 3 clinical trials, 96 sites enrolled subjects, 60 of which had no on-treatment pregnancies. Nineteen percent of the on-treatment pregnancies reported during this trial came from one site. This site represented approximately 8% of the randomized subject population. Thirty six percent of on-treatment pregnancies were reported at four of the 96 sites. These four sites represented approximately 15% of the randomized subject population.

Experts agree that the characteristic most likely to impact contraceptive failure and pregnancy rates is the subject's likelihood of using a method inconsistently or incorrectly. Consistent with expert opinions, our analyses have suggested that the results for both the patch and oral contraceptive control arms in the Phase 3 trials were also affected in part by the study population, which comprised a disproportionately high number of new users and minority subjects, known to be at higher risk of noncompliance and pregnancy, as compared to the majority of other recent CHC clinical trials which have gained approval in the United States.

Individuals who immediately switch from one hormonal contraception method to another, referred to as current users, or who have recently used another method of hormonal contraception, are less likely to experience contraceptive failure than a new user because they are less likely to have inconsistent or incorrect use. These experienced subjects are often selected for trial participation because their inclusion will lower failure rates. Indeed, many contraceptive trials have enrolled a high proportion of these subjects. Direct comparisons across multiple trials are limited by differences in study design and population, as well as differences in definitions of user status; however, as shown in the table below, some comparisons are possible. For example, when compared against trials that captured current hormonal contraceptive use, in the larger of our Phase 3 trials, we had a lower proportion of subjects randomized to receive Twirla that were current users, only 17.8%, reflecting a population with less experience using hormonal contraception, compared to two recently approved hormonal contraceptives. When compared against trials that categorized subject experience more broadly by their use of hormonal contraception within the 6 months prior to enrollment, our trial also had a lower proportion of experienced subjects, only 44%. In both the COC and Twirla groups, new users had approximately three times the rate of noncompliance compared to experienced users, as verified through blood tests revealing non-detectable blood levels of EE and LNG. Similarly, the pooled PI values from our Phase 3 clinical trials were more than twice as high among new users compared to experienced users, and in the primary efficacy analysis population there were no pregnancies observed in current users of other hormonal contraception who immediately switched to the patch upon entry into the trial.

In addition, our Phase 3 clinical trials also included a higher proportion of black and Hispanic subjects than most recent hormonal contraceptive trials. Although the underlying reasons are not well-understood, several articles in medical journals, such as *Contraception* and the *American Journal of Obstetrics & Gynecology*, and in at least one report by the U.S. Department of Health and Human Services, state that contraceptive failure rates are highest in black and Hispanic subjects. In our completed Phase 3 trials, rates of laboratory-verified noncompliance were substantially higher in blacks and Hispanics compared to non-Hispanic white subjects in the larger

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of our Phase 3 trials, and as shown in the table below, there were substantially higher PI values in the black and Hispanic subpopulations than in non-Hispanic white subjects. Additionally, as shown in the table the observed PI values were more dramatically increased for new users who were also black or Hispanic, which reinforces our need to closely monitor these subject demographics when enrolling the new trial.

Study Population Demographics in Selected Contraception Trials

		Contraceptive Product (Year of Approval) % of subjects in category*					
Parameter		**Twirla**	**Seasonique (2006)**	**Yaz (2006)**	**Lo-Seasonique (2008)**	**Natazia (2010)**	**Quartette (2013)**
Hormonal contraception use							
Current Users		18[a]		60[b]		59[c]	
Within 6m of enrollment	Yes[d]	44	68		61		44
	No[e]	56	32		39		56
Race/ethnicity	Hispanic	15	5	5	10	13	11
	Black	22	11	4	12	7	18

* Table includes subjects randomized to Twirla in our larger Phase 3 clinical trial. The data pertaining to the approved drug products were derived from multiple studies, with differing study designs, as reported in the FDA medical review documents for each product.

Current user definitions (extrapolated for approved products):

[a] Used a hormonal contraceptive within 7 days of enrollment.

[b] Using an oral contraceptive at screening, just prior to study start.

[c] Using oral contraceptives prior to study start.

Use within 6 months of enrollment definitions:

[d] Twirla: recent and current users; Quartette/Seasonique/Lo-Seasonique: continuous users.

[e] Twirla: new users; Seasonique/LoSeasonique: fresh start and prior users; Quartette: new start and prior user.

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Twirla Pearl Indices Stratified By New Users and Minority Subjects

Parameter	Demographic	Pearl Index*
Race/ethnicity	White (not Hispanic)	3.6
	Hispanic	5.0
	Black	15.1
Previous contraceptive use status	New users[a]	8.7
	Experienced users[b]	3.0
	Current users[c]	0.0
Race/ethnicity and Previous contraceptive use status	Hispanic subjects who were new users	7.5
	Black subjects who were new users	16.0

* Table includes the pooled PI values for subjects in the primary efficacy analysis population randomized to Twirla.

a New users = never used hormonal contraception or had not used hormonal contraception in the 6 months prior to enrollment.

b Experienced users = recent (used a hormonal contraceptive within 6 months of enrollment) and current users.

c Current users = subjects who used a hormonal contraceptive within seven days of enrollment.

CRL and Recent FDA Interactions

In February 2013, we received a CRL from the FDA indicating that the results from our completed Phase 3 trials would not be sufficient for approval, and the FDA proposed that we conduct an additional Phase 3 trial. Among the comments expressed in the letter were some regarding the PI values seen in the studies. Specifically, the FDA indicated that the PI values in the studies, in both the subjects using the Twirla patch and the control arm using oral contraceptives, were higher than seen in clinical trials used for registration of other approved hormonal contraceptives. 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.

In October 2013, we met with the FDA and received further guidance on requirements for our planned Phase 3 trial. In addition, we had a follow-up written interaction with the FDA in February 2014. Based on these discussions, we expect to enroll the first subject in our Phase 3 trial in the third quarter of 2014, and we anticipate completing the trial by the end of 2015. The patches that will be studied in our clinical trial will be laser etched using the same process as we

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anticipate for commercialization of Twirla, if approved. We also plan to conduct additional supportive testing in order to respond to the FDA's CMC questions.

Planned Phase 3 Clinical Trial

Our planned Phase 3 clinical trial is intended to address a number of issues identified in the CRL, including but not limited to, a simplified trial design, study conduct, recruitment of study population and compliance. Based on FDA guidance, we have designed our additional Phase 3 trial as follows:

- Single-arm study;
- Approximately 2,000 female subjects will receive Twirla for up to one year;
- 50 to 70 sites located in the United States with experience in conducting contraceptive studies;
- The subjects will be using an electronic diary to record the data that is critical to the calculation of the PI, such as sexual activity, back-up contraception use, and patch usage and adhesion; and
- We will assess patch adhesion based on a quantifiable daily subject assessment of percent adherence of the patch to the skin.

By not having a comparator, we will increase the number of cycles collected for the primary efficacy analysis. The single-arm design will also substantially reduce the complexity of statistical analyses required to interpret the results of the trial and will reduce uncertainty around interpretation of any unexpected differences in observed PI values between Twirla and a comparator arm that could occur. Importantly, the simplified protocol design should also be easier for clinical sites to understand and implement. In addition, we believe that having no oral contraceptive comparator will attract subjects who are interested in participating in the transdermal method as opposed to subjects who may be at higher risk for early discontinuation from the study if randomized to the patch. We believe this phenomenon occurred in the larger of our completed Phase 3 clinical trials and may have contributed to the early observed discontinuation rate.

The new study will be conducted with several measures put in place to improve upon one aspect of prior study conduct: loss to follow-up. First, the new study will be conducted in 50 to 70 sites in the United States that have experience conducting contraceptive trials and experienced study coordinators. Sites being considered for study participation will be evaluated extensively for their prior hormonal birth control trial experience through a data-driven approach assessing performance on previous clinical studies, staffing of experienced study coordinators with longevity at the site, demographics of potential study subjects, and audit history. Fewer sites will enable more focused oversight of participating sites and facilitate more individualized attention to enrolled study subjects, as compared to our previous Phase 3 study which was conducted at 96 sites. Training of study coordinators at the investigator meeting, at study initiation visits, and through ongoing communication should also reduce loss to follow-up. In addition, study sites that are showing early trends toward higher rates of loss to follow-up or overall poor study management will be re-trained and, if necessary, discontinued. Upon subject enrollment, sites will also ask for multiple methods of contact for each subject, and will obtain permission to contact family members and utilize public records to locate subjects who are lost to follow-up.

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After site selection, recruitment of the study population is the next crucial step toward achievement of a population that will provide reliable and generalizable data in our planned Phase 3 clinical trial. At the site level, selection of sites with a population of subjects that are experienced with use of contraceptives should contribute to the successful identification of subjects who have a higher likelihood of compliance and continuation in the study and will therefore be acceptable candidates for our trial. We will train our sites to provide individualized attention to recruitment of subjects who are most likely to adhere to the study protocol with respect to compliance, including correct patch application, timing of patch removal and replacement, electronic diary, or e-diary, completion and study visits. Potential subjects will be carefully screened for ability, motivation and willingness to comply with all of the study visits and other requirements. In order to ensure recruitment of acceptable subjects, study coordinators and investigators will receive in-depth training on selection of appropriate subjects prior to beginning subject enrollment, and these criteria will be reviewed throughout the study enrollment period. Subjects will also be advised through the informed consent process that noncompliance with study procedures may lead to discontinuation from the trial. In addition, each site will provide real-time recruitment information to the CRO throughout the recruitment process, which will facilitate enrollment of the appropriate subject population.

Once the subject population is selected, a number of measures will need to be put in place in order to facilitate compliance with study procedures. To ensure subjects are adequately educated regarding their responsibilities during the trial, a detailed subject teaching plan will be developed and implemented, and subject education regarding the importance of compliance, including videos, brochures and one-to-one education with study coordinators, will also be provided at repeated intervals throughout the study. A number of measures will be put in place to support and monitor compliance through the study. One key measure is the use of e-diary technology, which will allow for personalized reminders to subjects for patch application, diary completion and study visits, measures we believe will improve overall subject compliance. Additional methods of delivering reminders, for example, text messaging and email, will also be utilized. Phone contact with subjects between visits will also be added to the study protocol, which will increase the frequency of contact with subjects throughout the study.

In addition to contributing to improved compliance, the use of e-diary technology may also contribute to improved data quality and completeness in the next study. The e-diaries will be available on multiple platforms, including smartphones and tablets. Subjects will use their e-diaries to record the data that are critical to the calculation of the PI, including sexual activity and use of back-up contraception. Subjects will also record their bleeding patterns and patch adherence using a new, more precise scale. During the study screening period, subjects will receive comprehensive training on use of the e-diaries and will be required to demonstrate both appropriate use and ability to comply with the study protocol in order to be enrolled in the study. The diaries will be designed to be simple and easy-to-use, and to enhance data quality, will be designed with built-in prompts to avoid subject error in data entry. As the subjects enter data into the e-diaries, it will be uploaded into the CRO's database and will be available for real-time review by the CRO and our study monitors. The CRO and our study monitors will analyze individual subject and site data and can immediately implement additional training or intervention with study site coordinators and subjects as needed, including potentially discontinuing noncompliant sites or subjects. Real-time e-diary and study visit data will also potentially minimize the number of subjects lost to follow-up. By selecting an appropriate subject population and implementing the compliance

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measures described above, we anticipate that the number of pregnancies will be reduced as compared to the previous Phase 3 studies. None of these real-time measures were utilized in our previous clinical trials.

An independent Pregnancy Review Committee comprised of experts will also be selected to review all pregnancies and determine on or off-treatment status, which will affect the numerator of the PI calculation. The two most likely time periods for off-treatment pregnancies are between the screening visit for study entry and starting treatment with Twirla, and after completion of or discontinuation from the study. Accurate and timely pregnancy adjudication will be critically important in order to reduce the likelihood that pregnancies which occur during these time periods will be included by the FDA during the review process. In order to avoid unrelated pregnancies being included, every pregnancy will be assessed via ultrasound as soon as possible and full data will be collected regarding the relationship of the pregnancy to the subject's use of Twirla. Based on the observations regarding the clustering of pregnancies at a few sites during our completed Phase 3 trials, we believe that focused attention to ensuring full implementation of the compliance measures at every site will substantially reduce the overall incidence of pregnancies during the planned Phase 3 trial. We did not have an independent Pregnancy Review Committee for our previous clinical trials.

The observed PI values will not only be impacted by the number of pregnancies that occur in the study, but also by the number of cycles that are included in the analysis, which affects the denominator of the PI calculation. Cycles in which a subject is not sexually active, has incomplete diary information or uses a back-up method of contraception will not be counted toward the number of cycles included in the calculation of the PI. Indicators of subjects who are likely to exhibit the behaviors listed above will be carefully assessed during the recruitment process so as to reduce the number of cycles discarded from the analysis.

We plan to select a CRO with substantial experience in contraception studies and excellent site monitoring capabilities. We plan to actively participate in site selection, subject recruitment and site monitoring as well as oversight of the CRO throughout the length of the trial. Our CRO will be selected based not only on the above criteria, but on a clear track record of responding to trends and information through early intervention in order to assure compliance with trial procedures at both the subject and site levels.

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.

Twirla Line Extensions and Other Product Candidates

In addition to Twirla, our product pipeline consists of two classes of product candidates: Twirla line extensions and other transdermal contraceptive product candidates. These product candidates are designed to address market needs and offer additional non-daily contraceptive options.

The hormonal contraceptive market has a long history of manufacturers successfully using line extensions to extend the lifecycle of a brand, often by gaining additional exclusivity periods for the product extension under the provisions of the Hatch-Waxman Act or with additional patents. Our lifecycle strategy with Twirla is to introduce line extensions that will have exclusivity for some time period, either due to our intellectual property estate, or due to Hatch-Waxman exclusivity. The

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line extensions in our pipeline include using our Skinfusion technology to allow a shortened hormone-free interval, meaning fewer days of no hormones following the 21 days in the current Twirla regimen, as well as extending the cycle beyond the typical 28-day regimen to allow women to experience fewer withdrawal bleeds each year.

Our Twirla line extensions include the following:

- AG200-ER is an extended cycle regimen utilizing our current patch product designed to allow a woman to extend the time between her episodes of withdrawal bleeding. There are several currently approved oral contraceptives that provide an 84 or 91-day extended cycle regimen. However, there is no approved contraceptive patch product offering an extended cycle regimen. AG200-ER is a contraceptive patch which is designed to address the limitations of the currently approved extended regimen oral contraceptives by providing a more convenient, weekly dosing schedule. By adjusting the length of the cycle, AG200-ER is designed to potentially minimize breakthrough bleeding, which is a commonly-reported concern with patients using an extended regimen contraceptive product. We are currently evaluating the optimal cycle length to advance into clinical development. AG200-ER will utilize the same patch that is in the Twirla product, so this product has the potential to progress into clinical trials in 2015.

- AG200-SP is a 28-day regimen that includes a shortened hormone-free interval, or SHFI, designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy. AG200-SP may also provide benefit in patients with sensitivity to abrupt changes in hormone levels. The only currently approved products with a SHFI are oral contraceptives, and comprise 44% of U.S. TRx volume, demonstrating high acceptability among patients and providers. AG200-SP is designed to provide a simplified SHFI regimen through use of a smaller, lower-dose patch in the fourth week, which will allow patients to continuously apply patches without interruption. AG200-SP has the potential to occupy a unique position in this segment of the market, because it will allow for a reduced hormone interval through the delivery of lower, declining doses of one or both hormones EE and LNG.

Our other product candidate is a P-only contraceptive patch described below:

- AG890 is a LNG-only contraceptive patch, intended for use by women who are unable or unwilling to take estrogen, including those who are breastfeeding or who are at greater risk of VTE, such as women who smoke, are over 35 years of age, or who are obese. Currently, the P-only market consists of pills and several non-oral options, including IUDs, implants and injections. AG890 is intended to fulfill an unmet medical need for a non-daily, easily reversible form of contraception in the P-only market. We have conducted a Phase 1 clinical trial with AG890. In addition, the National Institutes of Health, through a clinical trial agreement with us, conducted a Phase 1/2 trial with AG890. The Phase 1/2 study was a multicenter study to evaluate the pharmacokinetics, safety and mechanisms of potential contraceptive efficacy of AG890. The trial is complete and data are currently being compiled. Early findings indicate that additional development will be required, including additional Phase 1 and Phase 2 studies to determine the optimal formulation and dose to advance to Phase 3.

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

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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 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.

Sales and Marketing

Twirla Commercialization Strategy

We expect to build a sales and marketing infrastructure in the United States to support the launch of Twirla for contraception, if approved. We anticipate that a targeted sales force focused initially on ObGyns, NPs, PAs and primary care providers who comprise the top prescribers of contraceptives will be highly effective. Outside the United States, in the future we may decide to commercialize Twirla, if approved, by entering into third-party collaboration agreements with pharmaceutical partners.

Twirla Promotion Strategy

We have employed several key strategies during the development of Twirla to prepare us for the launch of Twirla. These include:

- Seeking advice and input from key opinion leaders, or KOLs, in women's health and contraception;
- Sponsoring continuing medical education, or CME, programs at key congresses and symposia around the country;
- Establishing relationships with women's health advocacy groups;
- Conducting extensive market research to better understand the market dynamics and identify product positioning and messages for Twirla with prescribers and consumers;
- Assuring that data from our clinical trials are presented in a timely manner at clinical congresses and published in appropriate peer-reviewed medical journals; and
- Filing an intent-to-use application to register the trademark Twirla and developing key branding elements, including packaging design for submission with the NDA.

Prescribing in the CHC category is primarily driven by ObGyns, who write nearly 50% of the total prescriptions. In addition, NPs and PAs, who are often affiliated with an ObGyn practice but can also be in a primary care setting, also write contraceptive prescriptions. The ObGyns, NPs and PAs combine to write nearly 70% of total CHC prescriptions. In addition, 34% of all prescriptions written by ObGyns are for contraceptives. We plan to focus the promotion of Twirla on these key prescribers and other key customer groups, including consumers and commercial managed care plans. We believe that we can deploy a focused sales force effort targeting the approximately 22,000 prescribers responsible for 80% of branded CHC prescriptions. We believe that this universe of branded prescribers can be covered adequately by a specialty sales force of between 70 and 100 total representatives. In areas of the country where it is not efficient to deploy a sales representative, remote promotion can be used to reach these prescribers.

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We plan to deploy patient promotion at the launch of Twirla, both in the physician's office, and through targeted media campaigns. We plan to use both branded and unbranded campaigns to create awareness of Twirla among consumers. We believe there are cost-effective means to reach our target demographic of females aged 18 to 34 years, the so-called Millennials, who are more likely to seek health information online and through social networks. Traditional mass-market direct-to-consumer advertising on television may not be required to reach these consumers. Marketing tactics aimed at today's female consumer need to be optimized for mobile technology, because smartphones and text messaging are the preferred means of communication. Millennials also engage in online activities to a high degree. For example, approximately 80% use a social network and approximately 40% read blogs. We believe that a focused consumer promotion plan that uses digital media and other mass-market advertising vehicles will generate consumer awareness and demand for Twirla if approved.

Managed care plans have traditionally used differential co-pays to attempt to drive patients to use either generic products or products for which they have a contract with the manufacturer. Many plans encourage patients to obtain their branded contraceptives through mail-order, incentivizing them with a 90-day co-pay that is often less on a per-month basis than that for a 30-day supply. Most manufacturers of contraceptive brands offer a coupon to patients covered by non-governmental payors to offset the difference in co-pay between a generic and Tier 2 or Tier 3 for their promoted brands. These co-pay coupons are a useful tactic to overcome barriers to initiating therapy in such patients. When used in conjunction with product samples given out by the physician, a co-pay coupon often allows the patient to then fill their first prescription for free or at a steep discount, and limits the out of pocket expenditure for the patient for several months. This co-pay assistance creates brand loyalty, particularly for a brand where there is no generic alternative. We believe that we will be able to use free product samples and co-pay coupons or vouchers at the time of Twirla's launch to gain use of the product by patients covered by non-governmental payors while we are negotiating contracts with select commercial health plans and awaiting formulary review.

Market Research

We have conducted market research with healthcare professionals, consumers and managed care decision-makers to determine market drivers, unmet needs and the reaction to the Twirla product profile. A total of over 450 healthcare professionals and nearly 3,000 consumers have participated in our market research on Twirla and the contraceptive market. The main findings of the market research are discussed below.

Topline Summary of Our ObGyn/NP Market Research:

Compliance is a substantial problem with oral contraceptives, and many women are not comfortable with the "invasiveness" of a vaginal ring, IUD or implant.

The daily dose of estrogen delivered is the most important information requested by ObGyns and NPs in order for them to prescribe Twirla, if approved.

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- Prescribers need assurance that what happened with Evra will not occur with Twirla, although they are generally unable to state the actual EE dose delivered by Evra.

- ObGyns are not familiar with the PI calculation, and generally assume all FDA-approved contraceptives are about equally effective.

Two of our market research studies have included an allocation exercise to estimate the potential uptake of Twirla and peak market share. In both of these studies, ObGyns and NPs indicated their allocation of contraceptive prescriptions before and after reviewing a product profile like Twirla. In the first study, ObGyns estimated use of a product like Twirla in 17% of their CHC patients and in the second study, ObGyns and NPs estimated use of a product like Twirla in 18% of their contraceptive patients. A proprietary calibration model developed by Kantar Health was applied to the peak share estimate, to adjust for physician overstatement, resulting in an estimated peak market share of 9% of the CHC market. We believe a peak CHC market share of 9% can be achieved with Twirla within seven years of launch, allowing us time to establish a presence in the CHC market and to overcome any perceptions or barriers among prescribers due to the past history of Evra.

Topline Summary of Our Consumer Market Research:

- The most important benefit to consumers is the ability for Twirla to "make their life easier" and "take birth control off their minds."

- All women are "busy" and most women admit to missing at least one or more birth control pills every month.

- There is little to no awareness of Evra among consumers, and no pre-existing safety hangover to overcome.

- The fact that Twirla may minimize the 'black ring' effect is important.

- Among women who are currently considering starting prescription contraception, nearly half would be interested in using Twirla, and over 90% of those interested said they would discuss Twirla with their doctor.

Topline Summary of Our Managed Care Market Research:

- Contraceptives are not among the top categories affecting health plan budgets. New contraceptives will likely be subject to 'hands off' management by payors.

- Prior to formulary review, most commercial plans will add Twirla, if approved, to their system and reimburse the product as a non-preferred agent.

- Contracting is a critical driver to gain preferred formulary placement.

The managed care research summarized above was conducted prior to the implementation of the contraceptive mandate in the ACA. Managed care plans still appear to be to interpreting and addressing the extent to which they will cover contraceptives as required under the ACA. Market research conducted with pharmacy and medical directors in May 2013 revealed that only approximately 50% of payors interviewed had made a decision with regard to the management of contraceptives since the ACA became law. For the plans who have published their no cost preventive medications drug list, it appears that many are only offering generic oral contraceptives at a zero co-pay and that branded or non-oral contraceptive products are often available with a cost-sharing option, or at no cost with prior authorization from the prescriber.

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Competition

The industry for contraceptive products is characterized by intense competition and strong promotion of proprietary products. While we believe that our Skinfusion technology provides us with a competitive advantage, we face potential competition from many different sources, including large pharmaceutical companies, specialty pharmaceutical and generic drug companies, and medical device companies. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We face competition from a variety of non-permanent birth control products. There are barrier methods, such as the contraceptive sponge, diaphragm, cervical cap or shield and condoms. Then, there are hormonal methods, which is the category for our product candidates, such as oral contraceptives, injections, implants, IUDs and vaginal ring and transdermal contraceptive products.

The following table compares the effectiveness of birth control methods. We adapted the table from the World Health Organization, 2011 Family Planning Wall Chart.

Although there are over 180 CHC products, including branded and generics, available on the market today, approximately 50% of the total market sales, or $2.1 billion in 2013, consisted of

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sales of just eight products. Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The top selling product in the CHC market for the 12 months ending December 2013 was Nuvaring®, marketed by Merck, the only contraceptive ring available on the market, with over $550 million in sales for 2013. The Loestrin® franchise, marketed by Actavis, consisting of two oral contraceptives, Loestrin® 24 and LoLoestrin®, also totaled over $550 million in sales in 2013. Other competing products include: Gianvi® and Quartette®, marketed by Teva, Beyaz® and Yaz®, which totaled over $150 million in sales in 2013, and Mirena®, marketed by Bayer, Generess®, which had over $50 million in sales in 2013, marketed by Actavis, and Alesse®, marketed by Pfizer. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal and Mylan. Ortho Tri-Cyclen® Lo, also an oral contraceptive, had over $450 million in sales in 2013, and Ortho Evra®, launched in 2002 by Johnson & Johnson, the first contraceptive patch on the market, achieved $150 million in sales in 2013. It was the most successful product launch in the history of the U.S. contraceptive market, and the product rapidly gained annual sales levels of nearly $400 million by 2004. However, sales of that product declined rapidly following the emergence of safety concerns that were associated with the hightened levels of estrogen delivered by that product. In addition, Mylan announced the launch of a generic version of Evra in April 2014. Based on the market experience of other non-oral dosage forms, including the Evra product, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are other contraceptive products in development that, if approved, will compete with Twirla and our other product candidates. Companies that have new contraceptive products in various stages of development include Bayer's contraceptive patch and an oral contraceptive, each in Phase 3 development, Teva's oral contraceptive in Phase 3 development, Merck's oral contraceptive in Phase 3 development, Actavis' vaginal ring and P-only patch and an oral contraceptive in Phase 2 development, and Antares Pharma's transdermal gel contraceptive in Phase 2 development. However, in the past few years, some of these large pharmaceutical companies such as Johnson & Johnson and Pfizer have dissolved their women's health specialty marketing and sales teams, and Bayer has shifted their focus away from their CHC products to their IUD franchise.

We are aware of only one other CHC transdermal patch in development. This patch is being developed by Bayer, and contains the active ingredients EE and gestodene, a third generation progestin. Bayer has stated that their gestodene patch is small, round, and transparent, and delivers a daily EE dose comparable to a 20 microgram EE oral contraceptive. Phase 3 studies of the Bayer gestodene patch began in 2004, and they completed a Phase 3 efficacy trial in the United States in December 2010. Bayer also completed Phase 3 efficacy trials in the European Union, or E.U., and Latin America in September 2011, submitted a marketing application to the E.U. in September 2012, and received approval to market the gestodene patch in the E.U. in February 2014. At the time of the E.U. submission, Bayer reported that they were in talks with the FDA regarding a U.S. submission, but there has been no further public information regarding a U.S. submission or approval, and the most recent Bayer pipeline information does not list the gestodene patch.

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To date, there are no contraceptives containing gestodene available in the United States. We are aware that Wyeth was developing oral contraceptives containing gestodene in the late 1980s, with an NDA filed for an oral contraceptive containing gestodene and EE in 1988, and Wyeth planned filing an NDA for a second oral contraceptive containing gestodene in 1991. These products were never approved, and in a Wyeth pipeline report from 1996, there was no mention of any gestodene-containing product candidates among its contraceptives in development. Although not available in the United States, gestodene has been widely used outside the United States for a number of years. As with other third generation progestins, epidemiologic studies have reported a two-fold increase in risk of VTE with contraceptives containing gestodene compared to those containing LNG. We believe that if Bayer were to obtain FDA approval for the gestodene patch, the approved labeling may contain the same language that products containing third generation progestins have, which states that these contraceptives have a two-fold increase in risk of VTE as compared with contraceptives containing second generation progestins.

Manufacturing

We do not own any manufacturing facilities. We currently rely, and expect to continue to rely, on a third party for the manufacture of our product candidates for clinical trials, as well as for commercial manufacture if any of our product candidates receive marketing approval. In 2006, we entered into an exclusive agreement with Corium International, Inc., or Corium, to develop Twirla using our Skinfusion technology, and also for AG890, which is a P-only contraceptive patch in Phase 1/2 of clinical development. Our Corium agreement is an exclusive arrangement until Corium has commercially produced a significant, agreed-upon quantity of patches, currently projected to occur no earlier than five years following commercial launch of Twirla. Pursuant to the terms of our agreement, Corium is required to use commercially reasonable efforts to maintain sufficient manufacturing capabilities to supply the quantities of Twirla required for its initial commercial launch and commercial sales thereafter. We believe that our current manufacturing capacity at Corium should be able to meet all of the upcoming Phase 3 clinical trial needs. We intend to use a portion of the proceeds from this offering to invest in the Corium facility to complete the equipment validation and expansion of its manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla, if approved, which validation and expansion we expect to be completed in the second half of 2015. Corium is responsible for all aspects of Twirla manufacturing.

Strategic Agreements

Agreement with Corium

Pursuant to our manufacturing agreement, Corium's exclusive right to manufacture Twirla and AG890 extends until Corium has commercially produced a significant, agreed-upon quantity of patches, currently projected to occur no earlier than five years following commercial launch of Twirla, at which point the agreement will expire. The contract may be terminated by either party for the other party's uncured material breach. Following the end of the exclusivity period, if we were to seek a second source of supply, we would be required to obtain FDA approval through an NDA supplement for an additional manufacturing sites. The process of acquiring a second source of supply and obtaining FDA approval generally takes two years or more, and would require us to make substantial investments in new facilities and equipment.

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Under our agreement, Corium has performed process development and manufacturing of Twirla for each of our clinical trials. For the development work performed, we paid Corium for time and materials related to the achievement of certain development goals. To date, we have not made any milestone payments to Corium. Corium is not eligible for any milestone payments in the future. During 2012, we paid Corium an aggregate of $3.5 million towards leasehold improvements incurred by Corium to its facilities to provide for adequate manufacturing space for our product candidates.

In order to accommodate our anticipated commercial launch of Twirla, if approved, Corium has completed a substantial build-out of its facilities in Grand Rapids, Michigan, and it has installed over $10.0 million of equipment we purchased. This additional equipment and these facilities may require FDA pre-notification, pre-approval or inspection; however, we believe we can accomplish this expansion through an Annual Report filing to the Twirla NDA.

Reimbursement

Managed care plans have traditionally used differential co-pays to attempt to drive patients to use either generic products or products for which they have a contract with the manufacturer. Typically, a managed care plan's formulary is organized into between three and five tiers. Each tier is then associated with a set range of co-pay amounts, with products in the lower tiers having a lower co-pay. Many plans encourage patients to obtain their branded contraceptives through mail-order, incentivizing them with a 90-day co-pay that is often less on a per-month basis than that for a 30-day supply. Contraceptive brands are generally placed on Tier 2 only if there is a contract with the plan, although there are a few plans that place all branded products on Tier 2.

Managed care plans still appear to be to interpreting and addressing the extent to which they will cover contraceptives as required under the ACA. Market research conducted with Pharmacy and Medical Directors in May 2013 revealed that only approximately 50% of payors interviewed had made a decision with regard to the management of contraceptives since the ACA became law. For the plans that have published their no cost preventive medications drug list, it appears that many are only offering generic oral contraceptives at a zero co-pay and that branded or non-oral contraceptive products are often available at a cost-sharing option, or at no cost with prior authorization from the prescriber.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and

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regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold or termination, issuance of Warning, Untitled, or Cyber Letters, requests for product recalls, product seizures or detention, total or partial suspension or restriction of production, marketing or distribution, injunctions, fines, debarment, refusal to allow the import or export of product, adverse publicity, modification of promotional materials or labeling, refusals of government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, imprisonment, consent decrees and corporate integrity agreements, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

Submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;

Approval by an independent Institutional Review Board, or IRB, for each clinical site before each trial may be initiated;

Performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with cGCPs to establish the safety and efficacy of the proposed drug product for each indication;

Submission to the FDA of an NDA;

Satisfactory completion of an FDA advisory committee review, if applicable;

Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as the potential for completion of an FDA inspection of selected clinical sites to determine cGCP compliance; and

FDA review and approval of the NDA.

Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must

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resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of an investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB for each clinical trial site participating in the clinical trial must review and approve the plan for any clinical trial before it commences, and the IRB must continue to oversee the clinical trial while it is being conducted, including any changes. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered through controlled studies to a limited subject population with the target disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded subject population, generally at geographically dispersed clinical trial sites, in two adequate and well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product candidate. In the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and preclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the applicability of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur. Phase 1, Phase 2

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and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A user fee for the Twirla contraceptive patch was submitted with the original NDA. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA's standard review goal is to act on 90% of all applications within ten months of the 60-day filing date. We expect that our products, if and when approved, will be subject to a standard review goal.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. We believe that we may be able to obtain a waiver from the conduct of a PREA study as, historically, waivers have been granted for other contraceptive applicants.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held, as well as the manufacturing

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processes and controls, meet standards designed to ensure the product's continued safety, quality and purity.

The FDA may refer a marketing application to an external advisory committee for questions pertaining to issues such as clinical trial design, safety and efficacy, and public health questions. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it typically follows such recommendations and considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications by the manufacturer and all of its subcontractors and contract manufacturers. Additionally, before approving an NDA, the FDA will inspect one or more clinical trial sites to assure compliance with cGCP.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CRL. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information in order for the FDA to reconsider the application. We received a CRL for Twirla. We expect the FDA's CRL review timeline for Twirla to be approximately six months after submission of our response to the existing CRL. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product candidate, it may limit the approved indications for use of the product candidate and require that contraindications, warnings or precautions be included in the product labeling, including a black box warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Moreover, the FDA may require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include medication

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guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS could materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements, FDA notification, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for 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, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application 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. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it

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is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities, or NCEs, that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Our NDA for Twirla was submitted under Section 505(b)(2), and we expect that some of our other drug candidates will utilize the Section 505(b)(2) regulatory pathway. Even though several of our drug products utilize active drug ingredients that are commercially marketed in the United

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States in other dosage forms, we need to establish safety and efficacy of those active ingredients in the formulation and dosage forms that we are developing. All approved products, both innovator and generic, are listed in the FDA's Orange Book.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to manufacturing recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, reporting of adverse experiences with the product and drug shortages, and compliance with any post-approval requirements imposed as a condition of approval, such as Phase 4 clinical trials, REMS and surveillance to assess safety and efficacy after commercialization. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any approved products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, list drugs manufactured at their facilities with the FDA, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP and other requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing, distribution or manufacturing of the product, complete withdrawal of the product from the market or requests for product recalls;
- Fines, or Untitled, Cyber or Warning Letters or holds on or termination of post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties including disgorgement, restitution, fines and imprisonment;

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Consent decrees, corporate integrity agreements or exclusion from federal healthcare programs;

Debarment;

Mandated modification of promotional materials and labeling and the issuance of corrective information; or

The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment and refusal of government contracts.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufactures will have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Fraud and Abuse, Data Privacy and Security and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include, among other things, anti-kickback, physician payment transparency and false claims laws and regulations as well as data privacy and security laws and regulations.

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The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute and criminal healthcare fraud statutes was also amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses not expressly approved by the FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payor.

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In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes security standards and certain privacy standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws may govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, federal physician payment transparency laws, including the federal Physician Payment Sunshine Act created under Section 6002 of the ACA and its implementing regulations, require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report annually to the government information related to payments or other "transfers of value" made or distributed to physicians, which is defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors, generally, with some exceptions, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals. Additionally, applicable manufacturers and group purchasing organizations are required to report annually to the government certain ownership and investment interests held by physicians and their immediate family members, with data collection required as of August 1, 2013, and reporting to the government is required by March 31, 2014 and by the 90th day of each subsequent calendar year. Disclosure of such information is to be made on a publicly available website beginning in September 2014.

There are also an increasing number of analogous state laws that require manufacturers to file reports with states on pricing and marketing information, and to track and report gifts, compensation, other remuneration and items of value provided to healthcare professionals and healthcare entities. Many of these laws contain ambiguities as to what is required in order to comply with such laws. For example, several states have enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. These laws may affect our future sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions once we commercialize could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, refusal of government contracts,

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contract debarment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement Generally

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate coverage of and reimbursement levels for our product candidates. Government authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers and other third-party payors.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products, including pharmaceuticals. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in

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addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Healthcare Reform

Legislative proposals to reform healthcare or reduce costs under government healthcare programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. There have been a number of legislative and regulatory changes to the healthcare system that could affect our ability to profitably sell our product candidates, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and authorized Medicare Part D prescription drug plans to use formularies whereby they can limit the number of drugs that will be covered in any therapeutic class. As a result of the MMA and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in Medicare payments may result in a similar reduction in payments from non-governmental payors.

In March 2010, the ACA was enacted, which included provisions that have the potential to substantially change healthcare financing by both governmental and private insurers. The ACA, among other things, revised the methodology by which rebates owed by manufacturers to the Medicaid program for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. We cannot predict the full impact of the ACA on our business. Although the ACA may negatively increase manufacturers' rebate obligations under the Medicaid Drug Rebate Program, the ACA also extended coverage to millions of previously uninsured people, which may result in an increase in the demand for our product candidates.

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The ACA provisions on comparative clinical effectiveness research extended the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which provided $1.1 billion in funding to study the comparative effectiveness of healthcare treatments. This funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The ACA also appropriated additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of healthcare, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

It is possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates if they are approved.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in

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criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. For example, in the European Union, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $17.4 million for 2012 and $9.2 million for 2013. We plan to increase our research and development expenses for the foreseeable future as we seek to begin and complete our new Phase 3 clinical trial for Twirla and subsequently advance the development of our other product candidates.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover our Skinfusion technology, its methods of use, related technologies and other inventions that are important to our business. As more fully described below, our patents and patent applications are directed to our Skinfusion technology or aspects thereof including certain transdermal delivery systems having an active adhesive matrix and methods of using such transdermal delivery systems for controlling fertility. We also rely on manufacturing trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain new patents and maintain existing patents and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our product candidates. It may be necessary for us to use the

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patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We plan to continue to expand our intellectual property estate by filing patent applications directed to novel transdermal contraceptive products. The active pharmaceutical ingredients, or API, in our product candidates are generic and therefore our patents do not include claims directed solely to the API. We anticipate seeking additional patent protection in the United States and internationally for additional transdermal delivery systems and methods of their use.

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. Consequently, we do not know whether any of our product candidates will remain protected by enforceable and valid patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions generally are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of our entitlement to patent rights in the inventions covered in our issued patents and pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, USPTO, to determine priority of invention, or in post-grant challenge proceedings in the USPTO or a foreign patent office such as oppositions, reexamination, inter-partes review, post grant review, or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

More specifically, Twirla is a transdermal contraceptive hormone delivery system. The system is a patch for application to the skin and contains two API, the hormones levonorgestrel, which is a synthetic progestin, and ethinyl estradiol, a synthetic estrogen. The API are formulated with a combination of skin penetration enhancers, which promote penetration through the dermis and into the bloodstream, such that effective blood levels of the active agents are achieved to suppress ovulation and thereby prevent pregnancy. One of our other product candidates, AG890, is similar to Twirla, except that it contains only a single API, LNG.

In both our Twirla product candidate line and in AG890, the active adhesive system consists of the active ingredients in a polyacrylate adhesive polymer matrix comprising the permeation enhancers dimethylsulfoxide, ethyl lactate, capric acid and lauryl lactate. The active blend is coated onto a release liner, and a backing layer is added on top of the active blend. The peripheral adhesive system comprising three layers is added onto the backing layer. The overlay comprises a polyisobutylene adhesive layer, an acrylic adhesive layer, and an overlay covering. The overlay covering is a commercially available silk-like polyester fabric. The adhesive components of the overlay, in addition to their adhesive function, create an in situ seal with the disposable release

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liner, trapping evaporable solvents in the active blend, thereby extending the usable shelf life of the product candidate and contributing to the comfort and effectiveness of the transdermal system during use. Prior to use of any of our product candidates, the release liner is removed by the user and discarded. The patch is then applied to the skin.

Five patents, issuing from three patent families, have been submitted to the FDA for listing in the Orange Book upon approval of Twirla. These patents include claims directed to transdermal delivery systems having an active adhesive matrix and claims directed to methods of controlling fertility by applying such transdermal delivery systems, and in all cases including a skin permeation enhancer. Four of our five issued U.S. patents will expire March 14, 2021. The fifth issued U.S. patent will expire August 26, 2028.

U.S. Patent No. 7,045,145 is directed to the wet formulation of the transdermal delivery system used in Twirla, prior to drying, and expires in March 2021. U.S. Patent No. 7,384,650, U.S. Patent No. 8,221,784, and U.S. Patent No. 8,221,785 are all directed to the dry final product formulation of the transdermal delivery system used in Twirla, and expires in March 2021. U.S. Patent No. 8,221,784 covers both Twirla and AG890. Foreign counterparts to these patents have been granted in Australia, Canada, China, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, Norway, the Philippines, South Africa and Taiwan and are pending in other countries.

U.S. Patent No. 8,246,978 is directed to structural features of the transdermal delivery system used in Twirla and AG890 patch design for transdermal delivery of hormones or of other drugs. As such, this patent protects a platform technology for delivery of LNG, EE, other hormones, and other drugs. This patent expires in August 2028. Foreign counterparts are issued in New Zealand and are pending elsewhere.

A continuation application of this U.S. patent, U.S. Patent Application Publication No. 20130018337, has been allowed by a U.S. patent examiner and is expected to be issued soon. When issued, we expect to submit it for listing in the Orange Book. If granted, this patent would also expire in August 2028.

In addition, we own 40 issued patents in jurisdictions other than the United States, including patents in New Zealand, Australia, Canada, Austria, Belgium, Cyprus, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey, Indonesia, Israel, India, Japan, South Korea, Mexico, Norway, the Philippines, Taiwan and South Africa. These issued foreign patents include claims directed to transdermal delivery systems having an active adhesive matrix and claims directed to methods of controlling fertility by applying such transdermal delivery systems, and in all cases including a skin permeation enhancer. In addition, we have 33 pending patent applications in the United States and certain foreign jurisdictions for Twirla and AG890, and for unique patch dosage regimens intended to align with future label expansions and line extensions, such as AG200-ER and AG200-SP, including an anti-oxidant formulation and a desogestrel patch.

Regulatory Exclusivity

Our NDA for Twirla was submitted under Section 505(b)(2) of the FDCA. Even though Twirla utilizes API that were previously approved in the United States, Twirla utilizes LNG in a new dosage form, specifically a transdermal patch, and we provided new clinical data essential to

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approval in our NDA to establish the safety and efficacy of Twirla. Therefore, if approved by the FDA, we expect to receive three years of U.S. marketing exclusivity for Twirla. The exclusivity will prohibit the FDA from approving ANDAs and 505(b)(2) NDAs for the conditions of the Twirla approval. We will consider whether we are going to pursue patent term restoration, however, we are unsure whether such efforts will be successful.

Employees

As of April 15, 2014, we had 11 full-time employees. None of our employees is represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that we maintain good relations with our employees.

Properties

Our principal offices occupy approximately 7,000 square feet of leased office space in Princeton, New Jersey pursuant to a lease agreement that expires in November 2015. We believe that our current facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

We are not currently a party to any legal proceedings; however, we may become involved in various claims and legal actions arising in the ordinary course of business.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors, including their ages, as of April 15, 2014.

Name	Age	Position(s)
Executive Officers:		
Alfred (Al) Altomari	55	President, Chief Executive Officer and Director
Elizabeth Garner, M.D., M.P.H.	46	Senior Vice President and Chief Medical Officer
Scott M. Coiante	47	Vice President and Chief Financial Officer
Katie MacFarlane, Pharm.D.	48	Chief Commercial Officer
Non-Employee Directors:		
Abhijeet Lele(1)(2)	48	Director
Karen Hong, Ph.D.(1)(3)	42	Director
Lorenzo Pellegrini, Ph.D.(3)(4)	46	Director
Andrew Schiff, M.D.(1)(2)	48	Director
William T. McKee(2)(3)	52	Director

(1) Member of the compensation committee.

(2) Member of the audit committee.

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

(4) Dr. Pellegrini has informed the Board of his intention to resign from his position as a director of the Company immediately prior to the effectiveness of this Registration Statement.

Alfred Altomari has served as our Chief Executive Officer and as a member of our board of directors since October 2010. Prior to being named President and Chief Executive Officer, Mr. Altomari served as Agile's Executive Chairman from 2004 to 2010. From 2008 to September 2010, Mr. Altomari was also a consultant. From 2003 to 2008, Mr. Altomari held multiple senior management positions at Barrier Therapeutics, Inc., including Chief Commercial Officer, Chief Operating Officer, and Chief Executive Officer. In 2008, in his role as Chief Executive Officer and as a member of Barrier's board of directors, Mr. Altomari completed the successful sale of Barrier to Stiefel Laboratories, which was subsequently acquired by GlaxoSmithKline plc. From 1982 to 2003, Mr. Altomari held numerous executive roles in general management, commercial operations, business development, product launch preparation, and finance with Johnson & Johnson. Mr. Altomari also serves on the board of directors of Insmed Inc. and Recro Pharma, Inc. Mr. Altomari received an M.B.A. from Rider University and his B.S. from Drexel University. We believe that Mr. Altomari's experience in pharmaceutical companies with commercialized products, the launch of certain products and more than 20 years of focus on the development and marketing of specialty pharmaceutical products makes him uniquely suited to guide the Board in strategic planning, operational and commercial matters.

Elizabeth Garner, M.D., M.P.H. has served as our Chief Medical Officer since January 2014. Previously, she served as Vice President, Medical Affairs, Women's Health and Preventive Care at Myriad Genetics Laboratories from 2012 to 2014. From 2011 to 2012, she was Senior Medical

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Director, Women's Health at Abbott Laboratories where she served as the Clinical Lead, Endometriosis Program. Prior to that, Dr. Garner served as Associate Director and then Director, Vaccines Clinical Research at Merck Research Laboratories from 2007 to 2011. Dr. Garner received joint M.D. and M.P.H degrees from Harvard Medical School and the School of Public Health. She completed her residency in obstetrics and gynecology at Brigham and Women's/Massachusetts General Hospitals; her subspecialty fellowship in gynecologic oncology at Brigham and Women's and the Dana Farber Cancer Institute; and received board certification in both general Obstetrics and Gynecology and Gynecologic Oncology. Prior to entering the pharmaceutical industry, she had several years of experience in academic clinical practice, research and teaching at Harvard Medical School.

Scott M. Coiante has served as our Vice President and Chief Financial Officer since June 2011. He joined us in December 2010 and served as our Vice President of Finance between then and June 2011. Beginning in 2005, he served as Vice President Finance, Treasurer, Principal Accounting Officer at Medarex, Inc., a publicly listed biopharmaceutical company, which Bristol-Myers Squibb Co., acquired in September 2009 and during 2002 through 2005, he served as Director of Finance. While at Medarex, he was responsible for corporate financial functions including treasury, accounting, SEC reporting, tax and assurance. From 1989 to 2002, he held management positions of increasing responsibilities at Ernst & Young LLP, which included managing audit engagements, financial preparation, and financial reporting for client public offerings, both initial and follow-on, and SEC registration filing statements for both public and private companies, predominantly within the life science and pharmaceutical industries. He holds a B.S. in accounting from Villanova University.

Katie MacFarlane, Pharm.D. has been our primary commercial advisor since 2009, and most recently, became our Chief Commercial Officer in March 2014. Ms. MacFarlane also serves as a Managing Partner of SmartPharma LLC., a pharmaceutical consulting firm specializing in new product commercialization since 2007. Previously, she served as President and Chief Executive Officer at Xintria Pharmaceutical Corporation, a start-up company in the development of berberine for treatment of dyslipidemia and Type II diabetes from 2006 to 2008. Prior to that, Ms. MacFarlane served as Vice President of Women's Health and New Product Planning at Warner Chilcott, an international pharmaceutical company focused on women's healthcare, dermatology and urology from 2001 to 2006. From 1991 to 2000, she served in management positions of increasing responsibility in clinical research, marketing and sales management positions with the Parke-Davis, a division of Warner-Lambert and also held the position of Regional Sales Director and was responsible for sales force planning and implementation, including the integration with Pfizer, Inc., following the merger in 2000. Ms. MacFarlane received her B.S. degree in Pharmacy and Doctor of Pharmacy from Purdue University and completed a Postdoctoral Fellowship in Industrial Pharmacy Practice with Rutgers University and Hoffmann-LaRoche.

Abhijeet Lele has been a member of our board of directors since May 2010. Since 2009, Mr. Lele has served as a Managing Director and Head of Healthcare Investing at Investor Growth Capital, or IGC. IGC focuses on late-stage venture capital and growth equity investments in healthcare and technology companies. Before joining IGC, Mr. Lele spent ten years as a Managing Member of EGS Healthcare Capital Partners, or EGS, a venture capital firm focusing on private and public investments in biotechnology, specialty pharmaceutical and medical device

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companies. Prior to EGS, Mr. Lele was a consultant at McKinsey & Co., where he primarily served medical device, pharmaceutical and health insurance clients. He previously held operating positions with Lederle Laboratories, Inc., Progenics Pharmaceuticals, Inc. and Clontech Laboratories, Inc.. Mr. Lele previously served on the board of directors of Stereotaxis, Inc., Medarex Inc. and Aptalis Pharma Inc. He received an M.B.A. with Distinction from Cornell University and an M.A. from Cambridge University, where he studied Natural Sciences. We believe Mr. Lele's years of experience in the venture capital and healthcare industries make him qualified to serve on our Board.

Karen Hong, Ph.D. has served as a member of our board of directors since May 2006. Dr. Hong joined ProQuest Investments in 2001, was promoted to Principal in 2004, and to Partner in 2013. She and her team at ProQuest have guided over thirty investments to a successful exit and Dr. Hong has led working teams on many of these exits. Prior to joining ProQuest Investments, Dr. Hong provided technical consultation to the healthcare group at BancBoston Ventures and conducted biomedical research in cancer and mammalian genetics. Dr. Hong also serves on the board of directors of Clarus Therapeutics. Dr. Hong received a B.S. in chemistry and a B.A. in molecular biology from the University of California at Berkeley. She received a Ph.D. in biology from the Massachusetts Institute of Technology. Dr. Hong's scientific background and business experience, coupled with her experience as a venture capitalist advising life science and technology companies, provides her with the qualifications and skills to serve as a director.

Lorenzo Pellegrini, Ph.D. has served as a member of our board of directors since May 2010. Dr. Pellegrini currently serves as a Partner at Care Capital, a life sciences venture capital, where he joined the firm in 2003. Previously, from 1997 to 2001, Dr. Pellegrini was a post-doctoral research fellow in the Department of Cell Biology at Yale University, where he investigated the molecular basis of neuronal signaling and receptor internalization. During his ten-year tenure as an academic research scientist, Dr. Pellegrini published original research in several leading peer-reviewed scientific journals and was awarded a number of awards, including EMBO and Howard Hughes Medical Institute fellowships. Dr. Pellegrini holds a Laurea in Chemistry, summa cum laude, from the University of Padova, Italy, and a Ph.D. in Biochemistry from the Max-Planck-Institute for Brain Research in Frankfurt am Main, Germany, and an M.B.A. with Honors from The Wharton School of the University of Pennsylvania. We believe that Dr. Pellegrini's specialized experience in the biochemistry and chemistry disciplines, as well as his investment experience, make him qualified to serve on our Board.

Andrew Schiff, M.D. has served as a member of our board of directors since July 2012. Dr. Schiff joined Aisling Capital, a healthcare focused private equity firm, in September of 1999 and has served as a Managing Partner since 2002. Prior to Aisling Capital, Dr. Schiff practiced internal medicine at The New York Presbyterian Hospital where he maintains his position as a Clinical Assistant Professor of Medicine. Dr. Schiff currently serves as a director of Zeltiq Aesthetics as well as several other portfolio companies. Dr. Schiff received his M.D. from Cornell University Medical College, his M.B.A. from Columbia University, and his B.S. with honors in Neuroscience from Brown University. He is a long-time supporter of the Visiting Nurse Service of New York as well as other charitable organizations. We believe Dr. Schiff's medical background, venture experience, and myriad of directorships make him qualified to serve on our Board.

William T. McKee has served as a member of our board of directors since March 2014. Mr. McKee served as Chief Operating Officer and Chief Financial Officer for EKR

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Therapeutics, Inc., or EKR, from July 2010 until June 2012 when EKR was sold to Cornerstone Therapeutics Inc., or Cornerstone. He has served as a financial consultant to Cornerstone from June 2012 to the present. Until March 2010, Mr. McKee served as the Executive Vice President and Chief Financial Officer of Barr Pharmaceuticals, LLC, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, and the successor entity to Barr Pharmaceuticals, Inc., or Barr, an NYSE listed company, which was acquired by Teva in December 2008. Mr. McKee was also Executive Vice President and Chief Financial Officer of Barr prior to its acquisition by Teva, after having served in positions of increasing responsibility at Barr from 1995 until its acquisition. Prior to joining Barr, Mr. McKee served as Director of International Operations and Vice President-Finance at Absolute Entertainment, Inc. from June 1993 until December 1994. From 1990 until June 1993, Mr. McKee worked at Gramkow & Carnevale, CPA's, and from 1983 until 1990, he worked at Deloitte & Touche. Mr. McKee currently serves as a director of Auxilium Pharmaceuticals, Inc. Mr. McKee received his Bachelor of Business Administration degree from the University of Notre Dame. Through his years of experience as a chief financial officer and a public accountant, Mr. McKee provides valuable financial and leadership experience to the Board.

Composition of our Board of Directors

Our board of directors currently consists of six members, five of whom are members pursuant to the board composition provisions of our certificate of incorporation and our stockholders agreement, which agreement is described under "Certain Relationships and Related Party Transactions" in this prospectus. These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, and professional and personal experiences and expertise relevant to our growth strategy.

Immediately prior to the closing of this offering, our board of directors will be divided into three staggered classes of directors of the same or nearly the same number and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2015 for Class I directors, 2016 for Class II directors and 2017 for Class III directors.

Our Class I directors will be and ;

Our Class II directors will be and ; and

Our Class III directors will be and .

Our amended and restated certificate of incorporation and amended and restated by-laws provide that the number of our directors shall be fixed from time to time by a resolution of the

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majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Leadership Structure

The board of directors does not currently have a Chairman of the Board. We have a separate chair for each committee of our board of directors. The chairs of each committee are expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Director Independence

Under the listing requirements and rules of the NASDAQ Global Market, or NASDAQ, independent directors must compose a majority of a listed company's board of directors within a one year period following the completion of this offering. In addition, applicable NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees must be independent within the meaning of applicable NASDAQ rules. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act.

In 2014, our board of directors undertook a review of the independence of each director and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the association of our directors with the holders of more than 5% of our common stock. As a result of this review, our board of directors determined that Dr. Hong, Mr. Lele, Dr. Pellegrini, Dr. Schiff and Mr. McKee qualify as "independent" directors within the meaning of the NASDAQ rules. Although NASDAQ rules require that a majority of the board of directors and each member of our audit, compensation and nominating and corporate governance committees must be independent, under special phase-in rules applicable to new public companies, we will have until one year from the effective date of our initial public offering to comply with these independence requirements. As required under applicable NASDAQ rules, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. There are no family relationships among any of our directors or executive officers.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a charter adopted by our board of directors. Upon the closing of this offering, the composition and

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functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the NASDAQ Global Market and the SEC rules and regulations.

Audit committee. Mr. McKee, Dr. Schiff and Mr. Lele currently serve on the audit committee, which is chaired by Mr. McKee. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable NASDAQ Global Market rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated each of Mr. McKee and Dr. Schiff as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee operates under a written charter that satisfies the applicable standards of the SEC and NASDAQ and which will be available on our website prior to the completion of this offering at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and the independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases and scripts.

Compensation committee. Dr. Schiff, Dr. Hong and Mr. Lele currently serve on the compensation committee, which is chaired by Mr. Lele. Our board of directors has determined

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that each member of the compensation committee is "independent" as defined in the applicable NASDAQ Global Market rules. The compensation committee operates under a written charter that satisfies the applicable standards of NASDAQ and which will be available on our website prior to the completion of this offering at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. The compensation committee's responsibilities include:

- annually reviewing and making recommendations to the board of directors with respect to corporate goals and objectives relevant to the compensation of our chief executive officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and making recommendations to the board of directors with respect to the compensation of our chief executive officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K; and
- reviewing and discussing with the board of directors corporate succession plans for the chief executive officer and other key officers.

Nominating and corporate governance committee. Dr. Hong, Dr. Pellegrini and Mr. McKee currently serve on the nominating and corporate governance committee, which is chaired by Dr. Hong. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable NASDAQ Global Market rules. The nominating and corporate governance committee operates under a written charter that satisfies the applicable standards of NASDAQ and which will be available on our website prior to the completion of this offering at www.agiletherapeutics.com. The inclusion of our website address here and elsewhere in this prospectus does not include or incorporate by reference the information on our website into this prospectus. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;

identifying individuals qualified to become members of the board of directors;

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recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;

developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines;

developing a mechanism by which violations of the code of business conduct and ethics can be reported in a confidential manner; and

overseeing the evaluation of the board of directors and management

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, our code of business conduct and ethics will be available on our website at www.agiletherapeutics.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website.

Board Leadership Structure and Board's Role in Risk Oversight

The board of directors does not currently have a chairman of the board. However, in the past, the positions of chairman of the board and chief executive officer have historically been separated at Agile. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated by-laws and corporate governance guidelines do not require that our chairman and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our operations, strategic direction and intellectual property as more fully discussed under "Risk Factors" in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy

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itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on Agile, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables to the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Limitation of Liability and Indemnification Arrangements

As permitted by the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated by-laws that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated by-laws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the Delaware General Corporation Law; and
- advance expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also expect to enter into indemnification agreements with each of our executive officers and directors in connection with this offering. These agreements will provide that we will indemnify each of our directors to the fullest extent permitted by the Delaware General Corporation Law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

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We also maintain general liability insurance to provide insurance coverage to our directors and officers for losses arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling the registrant pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

These provisions may discourage stockholders from bringing a lawsuit against our directors in the future for any breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors, officers and certain employees pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that might result in a claim for such indemnification.

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EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2013 to (i) our chief executive officer, (ii) our other executive officer who was serving as an executive officer as of December 31, 2013, and (iii) our former Chief Medical Officer, who would have been one of the two highest-paid executive officers of the Company had she been employed by the Company as an executive officer at the end of the 2013 fiscal year. We refer to the foregoing as our named executive officers. We had no executive officers other than the named executive officers during the 2013 fiscal year.

Name and Principal Position	Salary ($)	Bonus ($)	Option Awards ($)(3)	All Other Compensation ($)	Total ($)
Alfred Altomari, ***President and Chief Executive Officer, Director***	$ 325,000	$ 65,000(1)			$ 390,000
Scott M. Coiante, ***Chief Financial Officer***	$ 225,000	$ 45,000(2)			$ 270,000
Marie Foegh, M.D. (4) ***Chief Medical Officer***	$ 187,500		$ 120,559(5)	$ 77,500(6)	$ 385,559

(1) Represents a discretionary bonus award earned by Mr. Altomari as a result of our performance in the 2013 fiscal year. Based on Mr. Altomari's election, all of the discretionary bonus award was paid in the form of 5,794 shares of our common stock on March 12, 2014. For further information, see " *2013 Bonus Program*" below.

(2) Represents a discretionary bonus award earned by Mr. Coiante as a result of our performance in the 2013 fiscal year. Based on Mr. Coiante's election, $30,000 of the discretionary bonus award was paid in cash, and the remaining portion of the bonus award was paid in the form of 1,337 shares of our common stock on March 12, 2014. For further information, see " *2013 Bonus Program*" below.

(3) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during fiscal year 2013 computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation of these amounts are included in Note 9 to our Financial Statements. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(4) Dr. Foegh's employment with the Company as its Chief Medical Officer ended effective September 30, 2013. On October 1, 2013, Dr. Foegh began a consulting relationship with the Company. For further information, see " *Dr. Marie Foegh*" below.

(5) Represents an option granted to Dr. Foegh pursuant to the terms of her consulting agreement with the Company. For further information, see " *Dr. Marie Foegh*" below.

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(6) Represents $15,000 of commuting assistance bonuses paid to Dr. Foegh from January 1, 2013 to September 30 , 2013 and $62,500 of salary continuation payments made to Dr. Foegh from October 1, 2013 to December 31, 2013 in connection with her separation from employment as Chief Medical Officer of the Company. For further information, see " *Dr. Marie Foegh*" below.

Arrangements with Our Named Executive Officers

2013 Bonus Program

In order to recognize the significant and numerous contributions of the executive officers and other key employees to the Company during the 2013 year, the Compensation Committee awarded discretionary bonuses in March 2014. In determining the amount to be paid to each executive officer, the Board of Directors considered the Company's performance in three areas: cash management, regulatory success and cultivation of strategic partnerships. In order to conserve the Company's cash reserves, all executive officers were provided with the opportunity to elect to receive shares of the Company's common stock in lieu of the cash bonus the officer otherwise would have received, based on the fair market value of the Company's common stock at the time the bonus was paid, as determined in good faith by our board of directors with the assistance of a third party valuation analysis.

Arrangements with Our Named Executive Officers

Alfred Altomari

On October 11, 2010, we entered into an agreement to employ Alfred Altomari as our Chief Executive Officer commencing as of that date. Prior to such time, Mr. Altomari served as the Executive Chairman of our Board of Directors. Mr. Altomari's employment agreement was amended on December 18, 2012, and has no specified term. Pursuant to the terms of the agreement, Mr. Altomari receives an annual base salary of $325,000, which may be adjusted at the discretion of the board of directors. Mr. Altomari is also eligible for an annual merit bonus with a target bonus opportunity of 40% of his base salary, payable at the discretion of the board of directors, if he achieves certain mutually agreed upon performance milestones established each fiscal year.

Pursuant to the terms of his employment agreement, we granted an option to Mr. Altomari under our 2008 Equity Incentive Plan to purchase 158,642 shares of common stock in December 2010. Mr. Altomari's option is subject to vesting through October 11, 2014. As of December 31, 2013, 127,794 shares subject to the option were vested and exercisable, and the remaining 30,848 shares shall vest and become exercisable in equal monthly installments through October 11, 2014. In addition, in the event of a change in control, Mr. Altomari's stock option to purchase 158,642 shares of the Company's common stock will become fully vested and exercisable. Mr. Altomari also holds options granted to him during his service as member of the Board of Directors prior to his employment as Chief Executive Officer of the Company and an option granted to him in 2012. For information regarding the treatment of Mr. Altomari's other stock options in the event of a change in control, please see " *2008 Equity Incentive Plan*" and " *1997 Equity Incentive Plan*" below.

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Payments Upon Termination Absent a Change in Control.

If Mr. Altomari terminates his employment for good reason or if we terminate his employment without reasonable cause (for any reason other than disability), in either case in the absence of a change in control, he is entitled to receive the following severance benefits: (i) base salary continuation for a period of 12 months, and (ii) benefit continuation for a period of 12 months following the date of his termination or until Mr. Altomari obtains other employment, whichever is sooner. In the event of a change in control following his termination, any base salary continuation payments still due to Mr. Altomari shall paid in full upon the change in control.

In the event Mr. Altomari's employment terminates as a result of his disability, he will be entitled to receive (i) base salary continuation for a period of 6 months following the date of his termination, and (ii) reimbursement of Mr. Altomari's health insurance premiums for a period of 6 months following the date of his termination due to his disability.

Payments Upon Termination in Connection with a Change in Control.

If Mr. Altomari terminates his employment for good reason or if we terminate his employment without reasonable cause, in either case upon or within 6 months following a change in control, he is entitled to receive the following severance benefits: (i) a lump-sum cash payment in the amount of 1.5 times his then annual rate of base salary, and (ii) benefit continuation for a period of 12 months following the date of his termination or until Mr. Altomari obtains other employment, whichever is sooner.

Notwithstanding the foregoing, any payments and benefits that would otherwise be paid to Mr. Altomari (whether or not under his employment agreement) in connection with a change in control of the Company will be reduced to the extent necessary to ensure that he is not subject to any excise tax under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment.

Under Mr. Altomari's employment agreement, the terms below are generally defined as follows:

"Change in Control" means (i) a merger or consolidation in which 50% or more of the voting securities of the Company are transferred and the composition of the Board after such transaction constitutes less than 50% of the members of the Board prior to the transaction; (ii) any acquisition, directly or indirectly, of beneficial ownership of 50% or more of the total combined voting power of the Company, other than in a capital-raising transaction; or (iii) the sale, transfer, exclusive worldwide license or other disposition of all or substantially all of the assets of the Company.

"Good reason" means Mr. Altomari's resignation following notice to the Company of, and failure by the Company to cure, the occurrence of any of the following: (i) an office relocation of more than 50 miles; (ii) failure by the Company to comply with any material term of the employment agreement; or (iii) the demotion to a lesser position or substantial diminution of authority, duties or responsibilities, except for a reduction in title, position, responsibilities or duties solely by virtue of the Company being acquired and made part of, or operated as a subsidiary of, a larger company, so long as the new duties and responsibilities are commensurate with Mr. Altomari's experience.

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"Reasonable cause" means (i) an act or omission that constitutes dishonesty, disloyalty, fraud, deceit, gross negligence, willful misconduct or recklessness and that is directly or indirectly materially detrimental to the Company's best interest; (ii) intentional failure to perform any lawful duties assigned by the Board after receiving notice and an opportunity to cure; (iii) the commission of any act that constitutes a felony; or (iv) any material breach of certain sections of the employment agreement.

The payment of any severance compensation described above is subject to Mr. Altomari's execution and non-revocation of a general release of claims against the Company, and his compliance with non-competition and non-solicitation restrictive covenants for a 1-year period following his termination date.

Scott M. Coiante

On November 23, 2010, the Company and Mr. Coiante executed an offer letter which governs the terms and conditions of Mr. Coiante's employment as Chief Financial Officer of the Company. Mr. Coiante's employment with the Company is at will and may be terminated at any time by the Company or Mr. Coiante. Pursuant to the terms of the offer letter, Mr. Coiante receives an annual base salary of $225,000. Mr. Coiante is also eligible for an annual bonus at a target rate of 25% of his base salary based on the achievement of individual and corporate objectives as determined by the board of directors. Upon the commencement of his employment on December 1, 2010, Mr. Coiante was paid a signing bonus of $10,000 pursuant to the terms of the offer letter.

In accordance with the terms of his offer letter, we granted an initial option to Mr. Coiante under our 2008 Equity Incentive Plan to purchase 17,047 shares of common stock in December 2010. As of December 31, 2013, 12,782 shares subject to the initial option were vested and exercisable, and the remaining 4,265 shares shall vest and become exercisable in equal monthly installments through December 2014. Pursuant to the terms of the offer letter, Mr. Coiante's initial stock option will become fully vested and exercisable in the event of a change in control, as defined in the Company's 2008 Equity Incentive Plan. Mr. Coiante also holds an option granted to him in 2012. For information regarding the treatment of Mr. Coiante's 2012 stock option in the event of a change in control, please see "*2008 Equity Incentive Plan*" below.

Pursuant to the terms of his offer letter, in the event Mr. Coiante is terminated without cause by the Company, he is entitled to receive salary continuation payments for a period of 3 months following the date of his termination, subject to his execution of a release of all claims against the Company. Under Mr. Coiante's offer letter, "cause" is generally defined as the Company's reasonable belief that one or more of the following have occurred: (i) habitual intoxication or abuse of a controlled substance; (ii) conviction of a felony involving moral turpitude: (iii) adjudication as an incompetent; (iv) breach of any material term set forth in the offer letter or the Non-Disclosure Agreement entered into by Mr. Coiante; (v) violation in any material respect of the Company's rules, regulations or policies; (vi) gross insubordination; (vii) engaging in any conduct, action or behavior that has had or may have a material adverse effect on Mr. Coiante's or the Company's reputation; (ix) continued or repeated unexcused absence; or (x) misappropriation of Company funds or property, theft, embezzlement or fraud.

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Marie Foegh, M.D.

On May 27, 2007, the Company and Dr. Foegh executed an offer letter providing the terms and conditions of Dr. Foegh's employment as the Chief Medical Officer of the Company. Dr. Foegh's employment as Chief Medical Officer ended on September 30, 2013 in accordance with the terms of a severance agreement and release dated September 30, 2013, and she began providing consulting services to the Company pursuant to a consulting agreement on October 1, 2013. Dr. Foegh earned $187,500 in base salary prior to September 30, 2013 and was paid salary continuation payments equaling $62,500 in the aggregate over the 3 month period measured from October 1, 2013 in accordance with her severance agreement.

In accordance with her consulting agreement, Dr. Foegh receives $350 per hour for her consulting services, and was granted an option to purchase 19,667 shares of common stock under the 2008 Equity Incentive Plan on October 1, 2013. 6,556 shares subject to Dr. Foegh's option will vest and become exercisable upon Dr. Foegh's continued service through September 30, 2014, and the remaining option shares will vest and become exercisable in 24 monthly installments over the 24-month period measured from October 1, 2014, provided that Dr. Foegh remains in service through each such vesting date. Pursuant to the terms of the offer letter, Dr. Foegh's stock option will become fully vested and exercisable in the event of a change in control, as defined in the Company's 2008 Equity Incentive Plan.

Elizabeth Garner, M.D., M.P.H.

On December 9, 2013 the Company and Dr. Garner executed an offer letter providing the terms and conditions of Dr. Garner's employment as our new Chief Medical Officer and Senior VP Clinical Development. Dr. Garner's employment with the Company is at will and may be terminated at any time by the Company or Dr. Garner. Pursuant to the terms of the offer letter, Dr. Garner is entitled to an annual base salary of $320,000 and is eligible for an annual bonus at a target rate of 25% of her base salary based on the achievement of individual and corporate objectives as determined by the board of directors. Upon the commencement of her employment on January 6, 2014, Dr. Garner was paid a signing bonus of $20,000; in addition, Dr. Garner is entitled to a quarterly $5,000 commuting allowance.

In accordance with the terms of her offer letter, we granted an initial option to Dr. Garner under our 2008 Equity Incentive Plan to purchase 44,600 shares of common stock. 22,300 of the shares subject to Dr. Garner's offer are subject to time-based vesting, with 25% of such option shares to vest and become exercisable upon Dr. Garner's completion of service to the Company through January 6, 2015, and the remaining option shares to vest and become exercisable in 36 equal monthly installments over the 36 month period thereafter. The remaining 22,300 shares subject of Dr. Garner's option shall vest and become exercisable following the completion of the Company's phase 3 clinical study of its Twirla contraceptive patch and the achievement of certain other related milestones. Pursuant to the terms of the offer letter, Dr. Garner's stock option will become fully vested and exercisable in the event of a change in control, as defined in the Company's 2008 Equity Incentive Plan.

Pursuant to the terms of her offer letter, in the event Dr. Garner is terminated without cause by the Company, she is entitled to receive, at the election of the Company, either salary continuation payments for a period of three months following the date of her termination or a

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lump sum payment upon her termination equal to three months of her base salary, subject to her execution of a release of all claims against the Company. Under Dr. Garner's offer letter, "cause" is generally defined as the Company's reasonable belief that one or more of the following have occurred: (i) habitual intoxication or abuse of a controlled substance; (ii) conviction of a felony involving moral turpitude: (iii) adjudication as an incompetent; (iv) breach of any material term set forth in the offer letter or the Non-Disclosure Agreement entered into by Dr. Garner; (v) violation in any material respect of the Company's rules, regulations or policies; (vi) gross insubordination; (vii) engaging in any conduct, action or behavior that has had or may have a material adverse effect on Dr. Garner or the Company's reputation; (ix) continued or repeated unexcused absence; or (x) misappropriation of Company funds or property, theft, embezzlement or fraud. Any payments and benefits that would otherwise be paid to Dr. Garner (whether or not under her offer letter) will be reduced to the extent necessary to ensure that she is not subject to any excise tax under Internal Revenue Code Section 4999.

Katie MacFarlane, Pharm.D.

On March 12, 2014, the Company and Ms. MacFarlane executed an offer letter providing the terms and conditions of Ms. MacFarlane's employment as our Chief Commercial Officer. Ms. MacFarlane's employment with the Company is at will and may be terminated at any time by the Company or Ms. MacFarlane. Pursuant to the terms of the offer letter, Ms. MacFarlane is entitled to an annual base salary of $180,000 and is eligible for an annual bonus at a target rate of 25% of her base salary, based on the achievement of individual and corporate objectives as determined by the board of directors. Ms. MacFarlane commenced her employment with the Company on March 17, 2014; prior to such date she served in a substantially similar role in the capacity of a consultant to the Company.

In accordance with the terms of her offer letter, we granted an initial option to Ms. MacFarlane under our 2008 Equity Incentive Plan to purchase 10,000 shares of common stock in March 2014. Twenty five percent of such option shares will vest and become exercisable upon Ms. MacFarlane's completion of service to the Company through March 17, 2015, and the remaining option shares will vest and become exercisable in 36 equal monthly installments over the 36 month period thereafter. Pursuant to the terms of the offer letter, Ms. MacFarlane's stock option will become fully vested and exercisable in the event of a change in control, as defined in the Company's 2008 Equity Incentive Plan.

Pursuant to the terms of her offer letter, in the event Ms. MacFarlane is terminated without cause by the Company, she is entitled to receive salary continuation payments for a period of three months following the date of her termination, subject to her execution of a release of all claims against the Company. Under Ms. MacFarlane's offer letter, "cause" is generally defined as the Company's reasonable belief that one or more of the following have occurred: (i) habitual intoxication or abuse of a controlled substance; (ii) conviction of a felony involving moral turpitude: (iii) adjudication as an incompetent; (iv) breach of any material term set forth in the offer letter or the Non-Disclosure Agreement entered into by Ms. MacFarlane; (v) violation in any material respect of the Company's rules, regulations or policies; (vi) gross insubordination; (vii) engaging in any conduct, action or behavior that has had or may have a material adverse effect on Ms. MacFarlane or the Company's reputation; (ix) continued or repeated unexcused absence; or (x) misappropriation of Company funds or property, theft, embezzlement or fraud.

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Any payments and benefits that would otherwise be paid to Ms. MacFarlane (whether or not under her offer letter) will be reduced to the extent necessary to ensure that she is not subject to any excise tax under Internal Revenue Code Section 4999.

Employee Confidentiality, Non-Competition, Non-Solicitation and Assignment Agreements

Each of our named executive officers has entered into a standard form agreement with respect to confidential information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the course of employment. Such agreement also provides that during the period of the named executive officer's employment and for 12 months thereafter, the named executive officer will not compete with us or solicit our employees, consultants, customers or suppliers.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of December 31, 2013.

		Option awards(1)			
	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable(2)	Option Exercise Price Per Share ($)(3)	Option Expiration Date
Alfred Altomari	01/24/2004	2		2,700.00	01/24/2014
	08/27/2004	7		400.00	08/27/2014
	03/28/2006	1		400.00	03/28/2016
	10/17/2006	10		400.00	10/17/2016
	04/24/2008	11		400.00	04/24/2018
	08/01/2008	77		400.00	08/01/2018
	03/18/2010	11,815		1.00	03/18/2020
	12/09/2010	127,802	30,840(4)	2.47	12/09/2020
	12/06/2012	87,381	99,865(4)	6.13	12/06/2022
Marie Foegh, M.D.	10/01/2013	19,667		6.13	10/01/2023
Scott M. Coiante	12/09/2010	12,782	4,265(4)	2.47	12/09/2020
	12/06/2012	8,751	9,982(4)	6.13	12/06/2022

(1) All of the option awards listed in the table above were granted under the 1997 Plan or the 2008 Plan, the terms of which are described below under " 1997 Equity Incentive Plan" and " 2008 Equity Incentive Plan", respectively.

(2) Except as otherwise indicated, all of the option awards listed in the table above are fully exercisable on the date of grant and vest with respect to 25% of the shares one year following the date of grant and with respect to 1/36th of the remaining shares on each monthly

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anniversary thereafter over the following three years, subject to the executive's continuous service with us through each vesting date.

(3) All of the option awards listed in the table above were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third party valuation analysis.

(4) The option award will become fully vested and exercisable in the event of a change in control of the Company.

Director Compensation

We did not pay any compensation to our non-employee directors for their service as board members during the 2013 fiscal year. We expect to adopt a formal director compensation policy prior to the completion of this offering.

2014 Incentive Compensation Plan

Introduction. We anticipate that our board will adopt and our stockholders will approve a 2014 Incentive Compensation Plan prior to the completion of this offering. We refer to the proposed 2014 Incentive Compensation Plan as the 2014 Plan.

Subject to board and stockholder approval, our 2014 Plan will become effective on the date of this offering. Our 2014 Plan is intended to serve as the successor to our 2008 Equity Incentive Plan and 1997 Equity Incentive Plan. The 2014 Plan will terminate no later than the tenth anniversary of this offering, unless extended with stockholder approval.

Share Reserve. We have initially reserved shares of our common stock for issuance under the 2014 Plan. Such share reserve is comprised of (i) the number of shares that were available for issuance in the aggregate under both the 2008 Equity Incentive Plan and the 1997 Equity Incentive Plan on the effective date of the 2014 Plan, including the shares subject to outstanding awards under those plans, that were transferred to the new 2014 Plan on the effective date (provided that such outstanding awards continue to be governed solely by the terms and conditions of their respective award agreements and plans), plus (ii) approximately additional shares of our common stock so that the initial total reserve of the 2014 Plan is at the share level.

The share reserve will automatically increase on the first trading day of January each calendar year during the term of the 2014 Plan by an amount equal to % of the total number of shares of our common stock outstanding on the last trading day of the immediately preceding calendar year. In no event, however, will any such annual increase exceed shares.

Incentive Programs. Our 2014 Plan is divided into three separate incentive compensation components:

the discretionary grant program under which eligible individuals in our employ or service may be granted options to purchase shares of our common stock or stock appreciation rights tied to the value of such common stock;

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the stock issuance program under which eligible individuals may be issued shares of our common stock, without the payment of a cash issuance price, pursuant to restricted stock awards, restricted stock units, performance shares or other stock-based awards which vest upon the attainment of pre-established performance objectives and/or the completion of a designated service period; and

the incentive bonus program which eligible individuals may earn cash bonus awards tied to the attainment of pre-established performance objectives.

Limitations. The 2014 Plan will impose the following limitations on the size of the awards which may be made on a per participant basis:

No one person may receive stock options and stand-alone stock appreciation rights for more than shares of our common stock in the aggregate per calendar year.

No one person may receive stock-based awards (other than stock options and stand-alone stock appreciation rights) for more than shares of our common stock in the aggregate per calendar year.

The maximum dollar amount for which a participant may receive awards denominated in dollars will be limited to $ in the aggregate per calendar year.

In addition, the maximum number of shares of our common stock that may be issued under our 2014 Plan pursuant to stock options intended to qualify as incentive stock options under the federal tax laws may not exceed shares. This share limitation, however, will automatically be increased on the first trading day in January each calendar year by the number of shares of our common stock added to the share reserve on that day pursuant to automatic share increase feature described above.

Eligibility. Officers and employees, non-employee members of our board of directors and independent consultants, in our employ or service or in the employ or service of our parent or subsidiary companies (whether now existing or subsequently established) are eligible to participate in the 2014 Plan.

Administration. The compensation committee of our board of directors has the exclusive authority to administer the plan with respect to awards made to our executive officers and non-employee board members and also has the authority to make awards under those programs to all other eligible individuals. However, our board of directors may at any time appoint a secondary committee of one or more board members to have separate but concurrent authority with the compensation committee to make awards under those programs to individuals other than our executive officers and non-employee board members. We refer to the particular entity carrying out its authorized administrative functions under the 2014 Plan, whether the compensation committee, the board, or a secondary committee, as the plan administrator. The plan administrator will determine which eligible individuals are to receive awards under those programs, the time or times when those awards are to be made, the number of shares subject to each such award, the applicable vesting, exercise and settlement schedules for each such award, the maximum term for which such award is to remain outstanding and the cash consideration (if any) payable per share.

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Plan Features. Our 2014 Plan includes the following features:

The exercise price for options and stock appreciation rights will not be less than the fair market value per share of our common stock on the grant date. No stock option or stock appreciation right will have a term in excess of ten years, and each grant will be subject to earlier termination following the recipient's cessation of service with us. The grants will generally vest and become exercisable in installments over the recipient's period of continued service. However, one or more awards may be structured so that those awards will vest and become exercisable only after the achievement of pre-established performance objectives.

Two types of stock appreciation rights may be granted:

Tandem rights, which provide the holders with the election to surrender their outstanding options for an appreciation distribution from us equal to the excess of (i) the fair market value of the vested shares subject to the surrendered option over (ii) the aggregate exercise price payable for those shares; and

Stand-alone rights, which allow the holders to exercise those rights as to a specific number of shares of our common stock and receive in exchange a distribution from us in an amount equal to the excess of (i) the fair market value of the shares as to which those rights are exercised over (ii) the aggregate exercise price in effect for those shares.

The appreciation distribution on any exercised tandem or stand-alone stock appreciation right may be paid in cash or shares of our common stock.

Under the stock issuance program, shares may be issued, without any cash payment required of the recipient, either as a stock bonus or pursuant to performance share awards, restricted stock or restricted stock unit awards or other stock-based awards which entitle the recipients to receive the underlying shares upon the attainment of designated performance objectives and/or the completion of a prescribed service period or upon the expiration of a designated time period following the vesting event.

Cash bonuses and performance units may be awarded under the incentive bonus program. Cash bonuses may be structured to vest and become payable upon the attainment of pre-established performance objectives and/or the completion of a designated service period. A performance unit will represent either (i) a unit with a dollar value tied to the level at which one or more pre-established performance objectives are attained or (ii) a participating interest in a special bonus pool funded on the basis of the levels at which the pre-established performance objectives are attained.

Performance objectives under the full value award and incentive bonus programs may be based on one or more of the following metrics: (i) revenue, organic revenue, net sales, or new-product revenue or net sales, (ii) achievement of specified milestones in the discovery and development of our technology or of one or more of the our products, (iii) achievement of specified milestones in the commercialization of one or more of our products, (iv) achievement of specified milestones in the manufacturing of one or more of the our products, (v) expense targets, (vi) share price, (vii) total shareholder return, (viii) earnings per share, (ix) operating margin, (x) gross margin, (xi) return measures (including, but not limited to, return on assets, capital, equity, or sales), (xii) productivity

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ratios, (xiii) operating income, (xiv) net operating profit, (xv) net earnings or net income (before or after taxes), (xvi) cash flow (including, but not limited to, operating cash flow, free cash flow and cash flow return on capital), (xvii) earnings before or after interest, taxes, depreciation, amortization and/or stock-based compensation expense, (xviii) economic value added, (xix) market share, (xx) working capital targets, (xxi) achievement of specified milestones relating to corporate partnerships, collaborations, license transactions, distribution arrangements, mergers, acquisitions, dispositions or similar business transactions and (xxii) employee retention and recruiting and human resources management. Each performance objective tied to one of the listed metrics may be structured to provide for appropriate adjustments or exclusions for one or more of the following items: (A) asset impairments or write-downs; (B) litigation and governmental investigation expenses and judgments, verdicts and settlements in connection therewith; (C) the effect of changes in tax law, accounting principles or other such laws or provisions affecting reported results; (D) accruals for reorganization and restructuring programs; (E) costs and expenses incurred in connection with mergers and acquisitions; (F) extraordinary or nonrecurring items; (G) bonus or incentive compensation costs and expenses, (H) items of income, gain, loss or expense attributable to the operations of any acquired or divested business and (I) the impact of foreign currency fluctuations or changes in exchange rates.

The plan administrator will have the discretion to waive the vesting requirements for any outstanding awards under the stock issuance or incentive bonus programs as to which the applicable service-vesting requirements are not met or the applicable performance objectives are not attained. Such waiver will result in the immediate vesting of each affected award. However, in general, no vesting requirements tied to the attainment of performance objectives may be waived with respect to awards which were intended at the time of grant to qualify as performance-based compensation under Internal Revenue Code Section 162(m).

Dividend equivalent rights may be issued made under the 2014 Plan. Each dividend equivalent right award will represent the right to receive the economic equivalent of each dividend or distribution, whether in cash, securities or other property (other than shares of our common stock) which is made per issued and outstanding share of common stock during the term the dividend equivalent right remains outstanding. Payment of the amounts attributable to such dividend equivalent rights may be made either concurrently with the actual dividend or distribution or may be deferred to a later date. Payment may be made in cash or shares of our common stock. The actual terms and conditions governing such dividend equivalent rights will be established by the plan administrator at the time those rights are awarded; provided, however, that no dividend-equivalent units relating to restricted stock unit or share right awards subject to performance-vesting conditions shall vest or otherwise become payable prior to the time the underlying award (or portion thereof to which such dividend-equivalents units relate) vests upon the attainment of the applicable performance goals and shall accordingly be subject to cancellation and forfeiture to the same extent as the underlying award.

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The 2014 Plan includes the following change in control provisions which may result in the accelerated vesting of outstanding awards:

Immediately prior to a change in control, each outstanding stock option or stock appreciation right which is not to be assumed by the successor corporation or otherwise continued in effect will automatically vest in full on an accelerated basis. However, the plan administrator has the authority to grant stock options or stock appreciation rights which will immediately vest immediately prior to a change in control, even if those awards are to be assumed by the successor corporation or otherwise continued in effect.

The plan administrator also has complete discretion to structure one or more stock options or stock appreciation rights so those awards will vest as to all the underlying shares in the event those awards are assumed or otherwise continued in effect but the individual's service with us or the acquiring entity is subsequently terminated within a designated period following the change in control event.

Outstanding awards under the stock issuance or incentive bonus program may be structured so that those awards will vest immediately prior to a change in control or upon a subsequent termination of the individual's service with us or the acquiring entity.

A change in control transaction will be deemed to occur should any of the following events occur: (i) we are acquired by merger or asset sale; (ii) any person or group of related persons becomes the beneficial owner of securities possessing more than fifty percent of the total combined voting power of all our outstanding securities or representing more than fifty percent of the aggregate market value of all our outstanding capital stock; or (iii) there occurs certain changes in the composition of our board of directors.

In the event any change is made to the outstanding shares of our common stock by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares, spin-off transaction or other change in corporate structure effected without our receipt of consideration or should the value of the outstanding shares of our common stock be substantially reduced by reason of a spin-off transaction or extraordinary dividend or distribution, equitable adjustments will be made to: (i) the maximum number and/or class of securities issuable under the 2014 Plan; (ii) the maximum number and/or class of securities by which the share reserve under the 2014 Plan may increase automatically each calendar year; (iii) the maximum number and/or class of securities which may be issued under the 2014 Plan pursuant to incentive stock options and the maximum number and/or class of securities by which that limitation automatically increases each calendar year; (iv) the maximum number and/or class of securities for which any one person may be granted stock options and stand-alone stock appreciation rights per calendar year; (v) the maximum number and/or class of securities for which any one person may be granted other stock-based awards per calendar year; (vi) the number and/or class of securities and the exercise price per share in effect for each outstanding stock option and stock appreciation right under the discretionary grant program; (vii) the number and/or class of securities subject to each outstanding full-value award under the stock issuance program and the cash consideration (if any) payable per share; and (viii) the number and/or class of securities subject to each outstanding award under the incentive bonus program denominated in shares of our common stock. These adjustments will be made in such manner as the plan

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administrator deems appropriate and will be binding on all persons with an interest in the 2014 Plan or any outstanding award under the 2014 Plan.

The plan administrator may provide for the automatic withholding of a portion of the shares otherwise issuable to participants in the 2014 Plan to satisfy the withholding taxes to which they become subject in connection with the issuance, exercise or vesting of their awards under such plan. Alternatively, the plan administrator may allow such individuals to deliver previously acquired shares of our common stock in payment of such withholding tax liability.

Subject to applicable law and regulations, the plan administrator may structure one or more awards under the plan so that the participants may be provided with an election to defer the compensation associated with those awards for federal income tax purposes.

The plan administrator does not have the authority, without stockholder approval, to (i) implement cancellation/regrant programs pursuant to which outstanding options or stock appreciation rights under the 2014 Plan are cancelled and new options or stock appreciation rights are granted in replacement with a lower exercise or base price per share, (ii) cancel outstanding options or stock appreciation rights under the 2014 Plan with exercise or base prices per share in excess of the then current fair market value per share of our common stock for consideration payable in cash or in equity securities of the company or (iii) reduce the exercise or base price in effect for outstanding options or stock appreciation rights under the 2014 Plan.

Unless sooner terminated by our board of directors or in connection with a change in control, the 2014 Plan will terminate on the tenth anniversary of this offering. However, any awards outstanding at the time of such plan termination will continue in force and effect in accordance with their existing terms.

Plan amendments will be subject to stockholder approval to the extent required by applicable law or regulation or the listing standards of the stock exchange on which our common stock is at the time primarily traded.

2008 Equity Incentive Plan

Our 2008 Equity Incentive Plan was approved by our board of directors on April 24, 2008, and was most recently amended in July 2012. We refer to our 2008 Equity Incentive Plan, as amended, as the 2008 Plan. We have reserved an aggregate of 1,110,750 shares of our common stock for the issuance of options and stock awards under the 2008 Plan. The maximum number of shares of our common stock that may be awarded to any one individual under the 2008 Plan during any calendar year is limited to 600,000 shares. The foregoing numbers are subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Effective upon the closing of this offering, our board of directors has determined not to grant any further awards under our 2008 Plan. The shares we issue under the 2008 Plan are authorized but unissued shares or shares we reacquire. The shares of common stock underlying any options that are forfeited, canceled, repurchased, expire or are otherwise terminated (other than by exercise) under the 2008 Plan are currently added back to the shares of common stock available for issuance under the 2008 Plan.

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The 2008 Plan permits us to grant incentive stock options and non-qualified stock options and allows us to issue shares of common stock to officers, employees, directors, consultants and other key persons (including prospective employees but conditioned upon their commencement of employment). Our 2008 Plan is administered by our board of directors. Our board of directors has the authority to select the individuals to whom awards will be granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award.

The exercise price of each option will be determined by our board of directors but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by the board of directors and may not exceed ten years from the date of grant. All stock option awards that are granted to employees are subject to the terms and conditions of a stock option agreement. Shares of common stock may be issued under the plan subject to such terms and conditions as may be determined by the board.

In the event of a change in control of the Company, the Board may take any of the following actions with respect to any or all outstanding awards under the 2008 Equity Incentive Plan: (i) determine that outstanding options shall accelerate and become exercisable, in whole or in part, upon the change of control or upon such other event as the Board determines, (ii) determine that the restrictions and conditions on outstanding stock awards shall lapse, in whole or in part, upon the change of control or upon such other event as the Board determines, (iii) require that grantees surrender their outstanding options in exchange for a payment by the Company, in cash or stock as determined by the Board, in an amount equal to the amount by which the then fair market value of the shares of common stock subject to the grantee's unexercised options exceeds the exercise price of the options, (iv) after giving grantees an opportunity to exercise their outstanding options, terminate any or all unexercised options at such time as the Board deems appropriate, or (v) provide that the outstanding options and stock awards will be assumed or otherwise continued in effect in connection with the change in control transaction.

Our board of directors may amend, suspend or terminate the 2008 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The board of directors may also amend, modify or terminate any outstanding award, provided that no amendment to an award may materially impair any of the rights of a participant under any awards previously granted without his or her written consent.

No awards may be granted under the 2008 Plan after the date that is 10 years from the date the 2008 Plan was approved by the stockholders. Our board of directors has determined not to make any further awards under the 2008 Plan following the closing of this offering.

1997 Equity Incentive Plan

Our 1997 Equity Incentive Plan was approved by our board of directors on December 5, 1997, and was most recently amended in May 2006. We refer to our 1997 Equity Incentive Plan, as amended, as the 1997 Plan. Pursuant to its terms, no awards may be granted under the 1997 Plan after December 4, 2007. As of December 31, 2013, 780 shares of common stock were subject to outstanding options granted under the 1997 Plan. The 1997 Plan permitted us to grant incentive stock options, non-qualified stock options and stock awards to officers, employees, directors, consultants and other key persons. The maximum number of shares of our common stock that

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could be awarded to any one individual under the 1997 Plan during any calendar year was limited to 20,000 shares. The terms and conditions of all outstanding stock options and stock awards granted under the 1997 Plan are substantially similar to the terms and conditions described above for awards granted under the 2008 Plan.

In the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company with or into another corporation, the Board may take such action with respect to options granted under the 1997 Plan as it deems desirable, including, but not limited to: (i) causing an option to be assumed or an equivalent option to be substituted by the successor corporation or a parent or subsidiary of such successor corporation, (ii) providing that an option holder shall have the right to exercise the option as to all of the shares of Common Stock covered by the option, including shares as to which the option would not otherwise be exercisable, or (iii) declaring that an option shall terminate at a date fixed by the Board provided that the option holder is given notice and opportunity to exercise the then exercisable portion of the option prior to such date.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2011 to which we were a party in which the amount involved exceeded or will exceed $120,000, and in which any of our executive officers, directors or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

Related Party Transactions

Consulting Agreement with SmartPharma LLC

Beginning on March 12, 2014, our board of directors appointed Katie MacFarlane as our Chief Commercial Officer, effective as of March 17, 2014. Ms. MacFarlane is also one of the Managing Partners of SmartPharma LLC, or SmartPharma. We entered into a consulting agreement with SmartPharma on October 16, 2009, which was subsequently amended on January 1, 2010 in order to engage SmartPharma to provide commercial and business development services. SmartPharma has invoiced us fees of $71,050 in 2014 as of the date of this prospectus, $347,498 in 2013, $377,450 in 2012, and $168,000 in 2011. All invoices received from SmartPharma as of April 15, 2014 have been paid in full. On December 6, 2012, we issued options to purchase 8,166 shares of our common stock with an exercise price of $6.13 per share with an expiration date of December 5, 2024 to SmartPharma, of which, Ms. MacFarlane directly received 4,083 of those options.

In connection with Ms. MacFarlane's appointment as our Chief Commercial Officer in March 2014, on March 1, 2014 we entered into a subsequent amendment to the consulting agreement between us and SmartPharma to remove Ms. MacFarlane from the list of persons providing service under the consulting agreement.

Series B Preferred Stock Financing

In May 2010, we entered into a Series B Preferred Stock Purchase Agreement, or the Series B Purchase Agreement, pursuant to which we initially issued and sold to investors an aggregate of 2,334,400 shares of Series B preferred stock at a purchase price of $10 per share, for aggregate consideration of approximately $23.3 million. At additional closings held between June 2010 and March 2012, we issued and sold an aggregate of 2,175,666 additional shares of Series B preferred stock at a purchase price of $10 per share, for aggregate additional consideration of approximately $21.8 million.

The participants in this convertible preferred stock financing included the following holders of more than 5% of our capital stock or entities affiliated with them. The participants in the Series B

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preferred stock financing included certain beneficial owners of more than 5% of our capital stock and entities affiliated with certain of our directors, as set forth in the table below:

Participants	Shares of Series B Preferred Stock
ProQuest Investments and its affiliates(1)	1,393,000
Care Capital Investments and its affiliates(2)	1,393,000
Investor Growth Capital and its affiliates(3)	1,393,000

(1) These shares of Series B preferred stock were purchased by ProQuest Investments III, L.P. and ProQuest Investments IV, L.P.

(2) These shares of Series B preferred stock were purchased by Care Capital Investments III LP and Care Capital Offshore Investments III LP.

(3) These shares of Series B preferred stock were purchased by Investor Growth Capital Limited and Investor Group, L.P.

May 2012 Convertible Note Financing

In May 2012, we entered into a Convertible Note Purchase Agreement, or the Note Purchase Agreement, pursuant to which we issued and sold to investors an aggregate principal amount of $6.0 million of convertible promissory notes (the "2012 Notes"). The aggregate principal amount of the 2012 Notes together with accrued interest thereon was converted to shares of our Series C preferred stock in July 2012 in connection with the issuance of our Series C preferred stock and none of the 2012 Notes remain outstanding.

The participants in this convertible promissory note financing included the following holders of more than 5% of our capital stock or entities affiliated with them. The participants in the convertible promissory note financing included certain beneficial owners of more than 5% of our capital stock and entities affiliated with certain of our directors, as set forth in the table below:

Participants	Principal Amount	Shares of Series C Preferred Stock Received on Conversion of Notes
ProQuest Investments and its affiliates(1)	$ 1,950,045	131,823
Care Capital Investments and its affiliates(2)	$ 1,798,424	121,573
IGC Fund VI, L.P.	$ 1,798,424	121,573

(1) These 2012 Notes were purchased by ProQuest Investments III, L.P. and ProQuest Investments IV, L.P.

(2) These 2012 Notes were purchased by Care Capital Investments III LP and Care Capital Offshore Investments III LP.

Series C Preferred Stock Financing

In July 2012, we entered into a Series C Preferred Stock Purchase Agreement, or the Series C Purchase Agreement, pursuant to which we issued and sold to investors an aggregate of 1,127,746

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shares of Series C preferred stock at a purchase price of $15 per share, for aggregate consideration of approximately $16.9 million. In addition, the aggregate principal amount of the convertible notes issued in May 2012, along with accrued interest, converted into an aggregate of 450,654 shares of Series C preferred stock at the same time.

The participants in this convertible preferred stock financing included the following holders of more than 5% of our capital stock or entities affiliated with them. The participants in the Series C preferred stock financing included certain beneficial owners of more than 5% of our capital stock and entities affiliated with certain of our directors, as set forth in the table below:

Participants	Shares of Series C Preferred Stock(1)
ProQuest Investments and its affiliates(2)	328,821
Care Capital Investments and its affiliates(3)	303,255
IGC Fund VI, L.P.	303,255
Aisling Capital III, LP	566,667

(1) Includes shares of Series C preferred stock issued pursuant to conversion of 2012 Notes described above.

(2) These shares of Series C preferred stock were purchased by ProQuest Investments III, L.P. and ProQuest Investments IV, L.P.

(3) These shares of Series C preferred stock were purchased by Care Capital Investments III LP and Care Capital Offshore Investments III LP.

Stockholders Agreement

We are party to a stockholders agreement under which certain holders of our capital stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, have agreed to, among other things, vote in a certain way on certain matters, including with respect to the election of directors. Upon the closing of this offering, the stockholders agreement will terminate and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

Registration Rights Agreement

We are party to a registration rights agreement that provides certain holders of our convertible preferred stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a more detailed description of these registration rights, please see "Description of Capital Stock Registration Rights."

Review and Approval of Related Party Transactions

Our Audit Committee Charter requires that our Audit Committee review and approve or ratify transactions involving us and any executive officer, director, director nominee, 5% stockholder and certain of their immediate family members, also referred to herein as a related

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person. The policy and procedures cover any transaction involving a related person, also referred to herein as a related person transaction, in which the related person has a material interest and which does not fall under an explicitly stated exception set forth in the applicable disclosure rules of the SEC.

A related person transaction will be considered approved or ratified if it is authorized by the Audit Committee after full disclosure of the related person's interest in the transaction. In considering related person transactions, the Audit Committee will consider any information considered material to investors and the following factors:

the related person's interest in the transaction;

the approximate dollar value of the transaction;

whether the transaction was undertaken in the ordinary course of our business;

whether the terms of the transaction are no less favorable to us than terms that we could have reached with an unrelated third party; and

the purpose and potential benefit to us of the transaction.

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PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of April 15, 2014 and on an as adjusted basis to reflect the sale of the common stock offered in this offering by:

- all persons known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares that an individual or entity has the right to acquire beneficial ownership of within 60 days of April 15, 2014 through the exercise of any warrant, stock option or other right. Unless otherwise indicated, the address of all listed stockholders is c/o Agile Therapeutics, Inc., 101 Poor Farm Road, Princeton, New Jersey 08540. Each of the stockholders listed has sole voting and investment

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power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Prior to the Offering	Percent of Class Prior to This Offering(1)	Percent of Class After This Offering(2)
(i) Certain Beneficial Owners:			
ProQuest Investments(3) 90 Nassau Street Fifth Floor Princeton, NJ 08542	1,983,032	30.4%	
Care Capital Investments(4) 47 Hulfish Street Suite 310 Princeton, NJ 08542	1,696,255	26.6%	
Investor Growth Capital(5) One Rockefeller Plaza Suite 2801 New York, NY 10020	1,696,255	26.6%	
Aisling Capital III, L.P.(6) 888 7th Avenue 30th Floor New York, NY 10106	566,667	8.9%	
(ii) Directors and Named Executive Officers			
Alfred Altomari(7)	290,761	4.4%	
Karen Hong, Ph.D.		*	
Abhijeet Lele		*	
Lorenzo Pellegrini, Ph.D.		*	
Andrew Schiff, M.D.		*	
William T. McKee		*	
Elizabeth Garner, M.D., M.P.H.		*	
Scott M. Coiante(8)	28,978	*	
Katie MacFarlane, Pharm.D.(9)	6,706	*	
(iii) All Directors and current executive officers as a group (9 persons)	326,445	4.9%	

*
Less than 1%

(1)
Our calculation of the percentage of shares beneficially owned before this offering is based on the number of shares of our common stock and common stock equivalents outstanding as of April 15, 2014. Our calculation includes 81,085 shares of common stock, 6,292,369 shares of common stock issuable upon the conversion of 137,787 shares of our Series A-1 convertible preferred stock, 66,116 shares of our Series A-2 convertible preferred stock, 4,510,666 shares of common stock issuable upon the conversion of our Series B convertible preferred stock

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and 1,578,400 shares of common stock issuable upon the conversion of our Series C convertible preferred stock.

(2)

For purposes of calculating the percentage of shares beneficially owned after this offering, the number of shares of common stock deemed outstanding after this offering assumes our issuance of shares of common stock in this offering. Each share of our Series A-1, A-2, B and C convertible preferred stock will automatically convert into one share of our common stock upon the closing of this offering. Warrants to purchase shares of our Series A-1 and Series A-2 convertible preferred stock will net exercise immediately prior to the closing of this offering into shares of convertible preferred stock that will subsequently be automatically converted into shares of common 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.

(3)

Includes (a) 1,945 shares of common stock, 1,353,502 shares of common stock issuable upon conversion of preferred stock and 141,825 shares of preferred stock issuable upon the exercise of preferred stock warrants, assuming the conversion of all such shares of preferred stock into 141,825 shares of common stock, held by ProQuest Investments III, L.P. and (b) 485,760 shares of common stock issuable upon conversion of preferred stock held by ProQuest Investments IV, L.P. Jay Moorin and Alain Schreiber, M.D. are managing members of ProQuest Associates III, LLC and ProQuest Associates IV, LLC, the general partners of ProQuest Investments III, L.P. and ProQuest Investments IV, L.P., respectively, and may be deemed to have shared voting, investment and dispositive power with respect to these shares.

(4)

Includes (a) 1,668,392 shares of common stock issuable upon conversion of preferred stock held by Care Capital Investments III LP and (b) 27,863 shares of common stock issuable upon conversion of preferred stock held by Care Capital Offshore Investments III LP. Care Capital III LLC is the general partner of Care Capital Investments III LP and Care Capital Offshore Investments III LP (collectively, "Care Capital") and as a result, Care Capital III LLC has the ultimate power to vote or direct the vote and to dispose or direct the disposition of such shares. Jerry N. Karabelas, Jan Leschly, Richard Markham and David R. Ramsay are the four managing members at Care Capital III LLC, and in their capacity as such, may be deemed to exercise shared voting and investment power over the shares held by the reporting persons, each of whom disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(5)

Includes (a) 714,727 shares of common stock issuable upon conversion of preferred stock, held by Investor Growth Capital Limited, (b) 306,312 shares of common stock issuable upon conversion of preferred stock held by Investor Group, L.P. and (c) 675,216 shares of common stock issuable upon conversion of preferred stock held by IGC Fund VI, L.P. Investor Growth Capital Limited is a Cayman Islands limited company and an indirectly wholly owned subsidiary of Investor AB, a publicly held Swedish company, Investor Group, L.P. is a Guernsey limited partnership of which Investor Growth Capital, LLC, a Delaware limited liability company which is indirectly wholly-owned by Investor AB, serves as the general partner and IGC Fund VI, L.P. is a limited partnership of which Investor Growth Capital, LLC, a Delaware limited liability company which is indirectly wholly-owned by Investor AB, serves as the general partner.

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(6) Consists of 566,667 shares of common stock issuable upon conversion of preferred stock. Aisling Capital Partners III, L.P. is the general partner of Aisling Capital III, L.P. Investment and voting decisions are made by an investment committee of Aisling Capital III, L.P., which currently consists of six members, including Dr. Schiff. The investment committee shares voting and dispositive power over the shares held directly by Aisling. Dr. Schiff disclaims beneficial ownership of the shares except to the extent of his indirect economic interests in Aisling and in connection with his role on the investment committee.

(7) Includes (a) 20,181 shares of common stock owned by Mr. Altomari, and (b) 270,580 shares of common stock that Mr. Altomari has the right to acquire from us within 60 days of April 15, 2014.

(8) Includes (a) 2,813 shares of common stock owned by Mr. Coiante and (b) 26,165 shares of common stock that Mr. Coiante has the right to acquire from us within 60 days of April 15, 2014.

(9) Represents 6,706 shares of common stock that Ms. MacFarlane has the right to acquire from us within 60 days of April 15, 2014.

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DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the completion of this offering. We have filed copies of these documents with the Securities and Exchange Commission as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

Upon consummation of this offering, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, and shares of preferred stock, par value $0.0001 per share, all of which preferred stock will remain undesignated.

As of December 31, 2013, we had outstanding:

73,954 shares of common stock, held by 23 stockholders of record;

6,292,369 shares of convertible preferred stock.

Upon the completion of this offering, all of the outstanding shares of our preferred stock will automatically convert into a total of 6,292,369 shares of our common stock.

In addition, as of December 31, 2013, we had outstanding options to purchase 831,158 shares of common stock. Immediately prior to the closing of this offering, warrants to purchase 180,018 shares of convertible preferred stock will be net exercised and will subsequently be automatically converted into shares of common stock immediately prior to the closing of this 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.

Common Stock

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to receive proportionately our net assets available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

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Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors will be authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors will have the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon completion of this offering, there will be no shares of preferred stock outstanding and we have no present plans to issue any shares of preferred stock.

Options

As of December 31, 2013, options to purchase 831,158 shares were outstanding at a weighted average exercise price of $4.81 per share, of which options to purchase 542,410 shares were exercisable. As of that date, an additional 279,592 shares were available for issuance under our 2008 Equity Incentive Plan.

Registration Rights

Upon completion of this offering, the holders of an aggregate of shares of our common stock that will be outstanding after this offering are entitled to require us to register the sales of their shares under the Securities Act, under the terms of an agreement between us and the holders of these securities. Subject to limitations specified in this agreement, these registration rights include the following:

two demand registration rights that holders may exercise no sooner than 180 days after our initial public offering, if a certain percentage of the holders request registration of shares with an aggregate offering price of $10,000,000, which require us to register sales of a holder's shares, subject to the discretion of our board of directors to delay the registration in specified circumstances;

an unlimited number of piggyback registration rights that require us to register a holder's shares whenever we register common stock (with certain limited exceptions), subject to the discretion of the managing underwriter of the offering to decrease the amount that holders may register; and

an unlimited number of rights (up to two per twelve-month period) to require us to register sales of shares on Form S-3, a short form of registration statement permitted to be used by some companies, which holders may exercise if a certain percentage of them request registration in connection with an aggregate offering of at least $5,000,000, following the time we first qualify for the use of this form of registration with the Securities and

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Exchange Commission, subject to the discretion of our board of directors to delay the registration in specified circumstances.

We will bear all registration expenses if these registration rights are exercised, other than underwriting discounts and commissions. These registration rights terminate as to a holder's shares when that holder may sell those shares under Rule 144(b)(1) of the Securities Act, which for most parties means one year after the acquisition of the shares from us.

Delaware Law and Certain Certificate of Incorporation and By-Law Provisions

The provisions of Delaware law and of our certificate of incorporation and by-laws discussed below could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or the best interests of Agile.

Business Combinations. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to specified exceptions, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's voting stock.

Limitation of Liability; Indemnification. Our certificate of incorporation contains provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate, to the extent legally permissible, a director's liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law. The limitation of liability described above does not alter the liability of our directors and officers under federal securities laws. Furthermore, our certificate of incorporation contains provisions to indemnify our directors and officers to the fullest extent permitted by the General Corporation Law of Delaware. These provisions do not limit or eliminate our right or the right of any stockholder of ours to seek non-monetary relief, such as an injunction or rescission in the event of a breach by a director or an officer of his duty of care to us. We believe that these provisions assist us in attracting and retaining qualified individuals to serve as directors.

Transfer Agent And Registrar

The transfer agent and registrar for our common stock is .

NASDAQ Market

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

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock, and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of common stock, including shares issued upon exercise of options and warrants, in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

Upon completion of this offering, we will have outstanding shares of common stock, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 6,292,369 shares of common stock and the net exercise immediately prior to the closing of this offering of warrants to purchase 205,020 shares of convertible preferred stock that will subsequently be automatically converted into shares of common 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.

Of these shares, the shares sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of common stock to be outstanding after this offering are "restricted securities" under Rule 144. All of these restricted securities will be subject to the 180-day lock-up period described below. After the 180-day period, shares will be freely tradable under Rule 144(b)(1) and shares will be eligible for resale under Rule 144, subject to volume limitations. An additional shares will become freely tradable under Rule 144(b)(1) in .

Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, which rules are summarized below.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, any person who is not deemed an affiliate during the preceding three months and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, subject only to the availability of current public information about us. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other

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than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of our common stock on NASDAQ during the four calendar weeks preceding the filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling on behalf of our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon expiration of the 180-day lock-up period described below, approximately shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 as currently in effect, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

Lock-up Agreements

In connection with this offering, we, our directors, our executive officers and all of our other stockholders have agreed with the underwriters, subject to certain exceptions that are described in more detail in the section in this prospectus entitled "Underwriting," not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives of the underwriters. Each of the underwriters has advised us that they have no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up period. The lock-up agreements permit stockholders to transfer common stock and other securities subject to the lock-up agreements in certain circumstances.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements and that there is no extension of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

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Registration Rights

Certain of our security holders have the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. See "*Description of Capital Stock Registration Rights*." Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration statement.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issuable under our equity incentive plans, including the equity incentive plans we plan to adopt in connection with this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. Our equity incentive plans are described in more detail under "Executive Compensation."

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MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock by "Non-U.S. Holders" (as defined below). This discussion is a summary for general information purposes only and does not consider all aspects of U.S. federal income taxation that may be relevant to particular Non-U.S. Holders in light of their individual circumstances or to certain types of Non-U.S. Holders subject to special tax rules, including partnerships or other pass-through entities for U.S. federal income tax purposes, banks, financial institutions or other financial services entities, broker-dealers, insurance companies, tax-exempt organizations, regulated investment companies, real estate investment trusts, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons who use or are required to use mark-to-market accounting, persons that hold our shares as part of a "straddle," a "hedge" or a "conversion transaction," certain former citizens or permanent residents of the U.S., investors in pass-through entities, or persons subject to the alternative minimum tax. In addition, this summary does not address the effects of any applicable gift or estate tax, and this summary does not address the potential application of the Medicare contribution tax or any tax considerations that may apply to Non-U.S. Holders of our common stock under state, local or non-U.S. tax laws and any other U.S. federal tax laws.

This summary is based on the Internal Revenue Code of 1986, as amended, or the Code, and applicable Treasury Regulations, rulings, administrative pronouncements and decisions as of the date of this registration statement, all of which are subject to change or differing interpretations at any time with possible retroactive effect. We have not sought, and will not seek, any ruling from the Internal Revenue Service, or the IRS, with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained. This discussion assumes that a Non-U.S. Holder will hold our common stock as a capital asset within the meaning of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for any Non-U.S. Holder under its particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income, estate and gift tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences.

For purposes of this discussion, the term "Non-U.S. Holder" means a beneficial owner of our shares that is not a U.S. person and is not a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes). A U.S. person is any one of the following:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in the U.S. or under the laws of the U.S. or of any state thereof or the District of Columbia;

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an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our common stock, the tax treatment of a partner in the partnership will generally depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. If you are a partner of a partnership holding our shares, you should consult your tax advisor regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Distributions on Our Common Stock

In general, distributions, if any, paid to a Non-U.S. Holder (to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles) will constitute dividends and be subject to U.S. withholding tax at a rate equal to 30% of the gross amount of the dividend, or a lower rate prescribed by an applicable income tax treaty, unless the dividends are effectively connected with a trade or business carried on by the Non-U.S. Holder within the U.S. Any distribution not constituting a dividend (because such distribution exceeds our current and accumulated earnings and profits) will be treated first as reducing the Non-U.S. Holder's basis in its shares of common stock, but not below zero, and to the extent it exceeds the Non-U.S. Holder's basis, as capital gain (see "*Gain on Sale, Exchange or Other Disposition of Our Common Stock*" below).

A Non-U.S. Holder who claims the benefit of an applicable income tax treaty generally will be required to satisfy certain certification and other requirements prior to the distribution date. Non-U.S. Holders must generally provide the withholding agent with a properly executed IRS Form W-8BEN claiming an exemption from or reduction in withholding under an applicable income tax treaty. This certification must be updated periodically. If a Non-U.S. Holder holds our common stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. If tax is withheld in an amount in excess of the amount applicable under an income tax treaty, a refund of the excess amount may generally be obtained by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under an applicable income tax treaty.

Dividends that are effectively connected with a Non-U.S. Holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a U.S. permanent

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establishment or fixed base of the Non-U.S. Holder) generally will not be subject to U.S. withholding tax if the Non-U.S. Holder provides the withholding agent with the required forms, including IRS Form W-8ECI, but instead generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates in the same manner as if the Non-U.S. Holder were a resident of the U.S. A corporate Non-U.S. Holder that receives effectively connected dividends may also be subject to an additional branch profits tax at a rate of 30% (or a lower rate prescribed by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

In general, a Non-U.S. holder will not be subject to any U.S. federal income tax or withholding tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

(i) the gain is effectively connected with a trade or business carried on by the Non-U.S. Holder within the U.S. (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base of the Non-U.S. Holder);

(ii) the Non-U.S. Holder is an individual who is present in the U.S. for 183 days or more in the taxable year of disposition and certain other conditions are met; or

(iii) we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held the common stock, and, in the case where shares of our common stock are regularly traded on an established securities market, the Non-U.S. Holder owns, or is treated as owning, more than five percent of our common stock at any time during the foregoing period.

Net gain realized by a Non-U.S. Holder described in clause (i) above generally will be subject to U.S. federal income tax in the same manner as if the Non-U.S. Holder were a U.S. person. Any gains of a corporate Non-U.S. Holder described in clause (i) above may also be subject to an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty.

Gain realized by an individual Non-U.S. Holder described in clause (ii) above will be subject to a flat 30% tax (or such lower rate specified by an applicable income tax treaty), which gain may be offset by certain U.S. source capital losses, even though the individual is not considered a resident of the U.S.

For purposes of clause (iii) above, a corporation is a "United States real property holding corporation" if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not, and we do not anticipate that we will become, a United States real property holding corporation. However, because the determination of whether we are a United States real property holding corporation depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a United States real property holding corporation in the future. If we become a United States real property holding

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corporation, as long as our common stock is regularly traded on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a Non-U.S. Holder that actually or constructively held more than 5% of our common stock at any time during the shorter of the two periods described in clause (iii), above. If gain on the sale or other taxable disposition of our common stock were subject to taxation under clause (iii) above, the Non-U.S. Holder would be subject to regular U.S. federal income tax with respect to such gain in generally the same manner as a U.S. person.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to each Non-U.S. Holder the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected with the Non-U.S. Holder's conduct of a trade or business within the U.S. or withholding was reduced by an applicable income tax treaty. Under applicable income tax treaties or other agreements, the IRS may make its reports available to the tax authorities in the Non-U.S. Holder's country of residence.

Dividends paid to a Non-U.S. Holder that is not an exempt recipient generally will be subject to backup withholding, currently at a rate of 28%, unless the Non-U.S. Holder certifies to the withholding agent as to its foreign status, which certification may generally be made on IRS Form W-8BEN or other appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding may apply if either we or our paying agent has actual knowledge, or reason to know, that the holder is a U.S. person that is not an exempt recipient.

Proceeds from the sale or other disposition of common stock by a Non-U.S. Holder effected by or through a U.S. office of a broker will generally be subject to information reporting and backup withholding, currently at a rate of 28%, unless the Non-U.S. Holder certifies to the withholding agent under penalties of perjury as to, among other things, its name, address and status as a Non-U.S. Holder or otherwise establishes an exemption. Payment of disposition proceeds effected outside the U.S. by or through a non-U.S. office of a non-U.S. broker generally will not be subject to information reporting or backup withholding if the payment is not received in the U.S. Information reporting, but generally not backup withholding (provided the broker does not have actual knowledge or reason to know that the holder is a U.S. person that is not an exempt recipient), will apply to such a payment if the broker has certain connections with the U.S. unless the broker has documentary evidence in its records that the beneficial owner thereof is a Non-U.S. Holder and specified conditions are met or an exemption is otherwise established.

Backup withholding is not an additional tax. Any amount withheld under the backup withholding rules from a payment to a Non-U.S. Holder that results in an overpayment of taxes generally will be refunded, or credited against the holder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

Foreign Accounts

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a "foreign financial institution" (as specially defined under applicable rules) unless such institution enters into an agreement with the U.S. government

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to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to payments of dividends and the gross proceeds of a disposition of our common stock paid to a "non-financial foreign entity" (as specially defined under applicable rules) unless such entity either certifies it does not have any substantial U.S. owners or provides the withholding agent with a certification identifying substantial direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. The U.S. has entered into agreements with certain countries that modify these general rules for entities located in those countries. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

The withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of our common stock on or after January 1, 2017. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding these withholding provisions.

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UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, to be dated the date of the final prospectus, between us and RBC Capital Markets, LLC and William Blair & Company, L.L.C., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
RBC Capital Markets, LLC	
William Blair & Company, L.L.C.	
Cantor Fitzgerald & Co.	
Janney Montgomery Scott LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not expect sales to accounts over which they have discretionary authority to exceed 5% of the common stock being offered.

Commissions and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. After the offering, the initial public offering price and the

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concession to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $ million. We have agreed to reimburse the underwriters for certain expenses in an amount up to $.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

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

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above.

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This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of substantially all of our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer to sell, contract or grant any option to sell, effect any short sale, grant any option, right or warrant to purchase, pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act, lend or otherwise dispose of, or enter into any swap, hedge or similar arrangement that transfers, in whole or in part, the economic consequences of ownership of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially,

- file a registration statement with the SEC relating to the offering and sale of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock, or

- publicly announce any intention to do any of the foregoing,

for a period of 180 days after the date of this prospectus without the prior written consent of the representatives.

The lock-up restrictions terminate after the close of trading of the common stock on and including the 180th day after the date of this prospectus. The representatives may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. These restrictions apply to shares of our common stock purchased in this offering by certain holders for a period of 90 days after the date of this prospectus.

The restrictions described above to do not apply to:

- transactions relating to shares of our common stock or other securities acquired in open market transactions after the completion of this offering;

- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, as a bona fide gift, by will or intestacy or to a family member or trust, partnership, limited liability company or other entity for the direct benefit of the lock-up signatory or a family member;

- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock to a charity or educational institution;

- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, to any shareholder, partner or member of, or owner of similar equity interests in, a holder, if the holder controls, directly or indirectly, any corporation, partnership, limited liability company or other business entity;

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transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, to affiliates of or any investment fund or other entity controlled or managed by a holder;

transfers to us for the purpose of satisfying tax withholding obligations upon the vesting of other equity incentive awards granted under any existing stock incentive plan or stock purchase plan described in this prospectus;

transfers to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible;

transfers of shares of our common stock, or any securities convertible into, exercisable or exchangeable for our common stock, pursuant to an order of a court or regulatory agency; or

transfers, sales, tenders or other dispositions of shares of our common stock, or any securities convertible into, exercisable or exchangeable for our common stock, occurring after the consummation of this offering, pursuant to a bona fide third-party tender offer for our securities that would result in the disposition of not less than a majority of the outstanding shares of our voting securities, or pursuant any other transaction, including a merger, consolidation or other business combination, resulting in a disposition of not less than a majority of the outstanding shares of our voting securities (including entering into any lock-up, voting or similar agreement to transfer, sell, tender or otherwise dispose of any shares of our common stock, or to vote any shares of our common stock in favor of such a transaction), provided that in the event that such tender offer, merger, or transaction is not completed, our common stock and any security convertible into or exchangeable for our common stock shall remain subject to the same restrictions,

provided, *however*, that in the case of any transfer or distribution pursuant to the second, third, fourth, fifth, sixth, seventh and eighth clauses above, each donee, distributee or transferee shall sign and deliver a lock-up agreement substantially in the form of the lock-up agreements described above; and in the case of any transfer or distribution pursuant to the second, third, fourth, fifth, sixth and seventh clauses above, such transfer or distribution shall (i) not involve a disposition for value and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock, shall be required or shall be voluntarily made during the restricted period.

There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

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"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment

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banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Notice to Residents of Canada

The securities may be sold only to purchasers purchasing as principal that are both "accredited investors" as defined in National Instrument 45-106 Prospectus and Registration Exemptions and "permitted clients" as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

Notice to Prospective Investors in the EEA

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, which we refer to as a Relevant Member State, an offer to the public of any shares of common stock that are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

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(c) by the underwriters to fewer than 100 natural or legal persons (other than "qualified investors" as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of shares shall result in a requirement for the publication by us or any representative of a prospectus pursuant to Article 3 of the Prospectus Directive.

Any person making or intending to make any offer of shares within the EEA should only do so in circumstances in which no obligation arises for us or any of the underwriters to produce a prospectus for such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares through any financial intermediary, other than offers made by the underwriters which constitute the final offering of shares contemplated in this prospectus.

For the purposes of this provision, and your representation below, the expression an "offer to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any shares under, the offer of shares contemplated by this prospectus will be deemed to have represented, warranted and agreed to and with us and each underwriter that:

(a) it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and

(b) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than "qualified investors" (as defined in the Prospectus Directive), or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or (ii) where shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those shares to it is not treated under the Prospectus Directive as having been made to such persons.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or

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elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571 Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares of common stock may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the Offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust

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has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, which we refer to as the Order, or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The Prospectus does not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations ("CO") and the shares will not be listed on the SIX Swiss Exchange. Therefore, the Prospectus may not comply with the disclosure standards of the CO or the listing rules (including any prospectus schemes) of the SIX Swiss Exchange. Accordingly, the shares may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors, which do not subscribe to the shares with a view to distribution.

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LEGAL MATTERS

Certain legal matters with respect to the validity of the shares of common stock offered hereby will be passed upon for us by Morgan, Lewis & Bockius LLP, Princeton, New Jersey. Certain legal matters related to this offering will be passed upon for the underwriters by Latham & Watkins LLP, Boston, Massachusetts.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2012 and December 31, 2013, and for each of the two years in the period ended December 31, 2013 as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the financial statements). We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

The statement of stockholders' deficit and the statements of operations and cash flows (not separately presented herein) for the cumulative period from December 22, 1997 (inception) to December 31, 2008 of Agile Therapeutics, Inc. (a development stage enterprise), have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein which report includes an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered in this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the accompanying exhibits and schedules. Some items included in the registration statement are omitted from this prospectus in accordance with the rules and regulations of the SEC. For further information with respect to us and the common stock offered in this prospectus, we refer you to the registration statement and the accompanying exhibits and schedules. Statements contained in this prospectus as to the contents of any contract, agreement or any other document are summaries of the material terms of these contract, agreement or other document. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to such exhibit for a more complete description of the matter involved. A copy of the registration statement, and the accompanying exhibits and schedules, may be inspected without charge and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is http://www.sec.gov.

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Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and we will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at http://www.agiletherapeutics.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Financial Statements

Years Ended December 31, 2012 and 2013 and
Period From December 22, 1997 (Inception) to December 31, 2013

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Report of Independent Registered Accounting Firm

The Board of Directors and Stockholders
Agile Therapeutics, Inc.

We have audited the accompanying balance sheets of Agile Therapeutics, Inc. (a development stage enterprise) as of December 31, 2012 and 2013, and the related statements of operations, convertible preferred stock and changes in stockholders' deficit and cash flows for each of the two years in the period then ended, and for the period December 22, 1997 (inception) through December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements as of for the period December 22, 1997 (inception) through December 31, 2008, were audited by other auditors whose report dated March 14, 2014 expressed an unqualified opinion on those statements. The financial statements for the period December 22, 1997 (inception) through December 31, 2008 include total operating expenses and net loss of $35,153,943 and $36,580,624, respectively. Our opinion on the statements of operations, convertible preferred stock and stockholders' deficit and cash flows for the period December 22, 1997 (inception) through December 31, 2013, insofar as it relates to amounts for prior periods through December 31, 2008, is based solely on the report of other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors the financial statements referred to above present fairly, in all material respects, the financial position of Agile Therapeutics, Inc. at December 31, 2012 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2013 and for the period from December 22, 1997 (inception) through December 31, 2013, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and will require additional funding in the future. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Metro Park, New Jersey
March 17, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Agile Therapeutics, Inc.

We have audited the statement of stockholders' deficit and the statements of operations and cash flows (not separately presented herein) for the cumulative period from December 22, 1997 (inception) to December 31, 2008 of Agile Therapeutics, Inc. (a development stage enterprise) (the "Company"). The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of the Company's operations and its cash flows for the cumulative period from December 22, 1997 (inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses from operations and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. Management's plans with respect to these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP
Iselin, New Jersey
March 14, 2014

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Balance Sheets

	December 31		Pro forma December 31, 2013
	2012	2013	(Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 20,013,754	$ 2,119,646	$
Prepaid expenses and other current assets	254,103	146,704	
Total current assets	20,267,857	2,266,350	
Property and equipment, net of accumulated depreciation of $261,215 in 2012 and $273,092 in 2013	7,029,576	11,963,079	
Deferred financing costs, net	202,499	157,499	
Other assets	18,208	18,208	
Total assets	$ 27,518,140	$ 14,405,136	$
Liabilities, convertible preferred stock and stockholders' deficit			
Current liabilities:			
Accounts payable	$ 1,126,931	$ 715,454	$
Accrued expenses	416,435	379,164	
Loan payable, current portion		5,105,407	
Warrant liability	563,488	644,478	
Total current liabilities	2,106,854	6,844,503	
Loan payable, long-term	14,787,024	9,769,528	
Commitments and contingencies *(Note 11)*			
Series A-1, 8%, non-cumulative convertible preferred stock, $.0001 par value, authorized 284,743 shares; issued and outstanding 137,787 shares in 2012 and 2013 (liquidation preference of $1,377,870 at December 31, 2013); no shares issued or outstanding, pro forma	898,305	898,305	
Series A-2 convertible preferred stock, $.0001 par value, authorized 99,178 shares; issued and outstanding 66,116 shares in 2012 and 2013 (liquidation preference of $661,160 at December 31, 2013); no shares issued or outstanding, pro forma	543,623	543,623	
Series B, 8% non-cumulative, convertible preferred stock, $.0001 par value, authorized 4,510,066 shares; issued and outstanding 4,510,066 shares in 2012 and 2013 (liquidation preference of $45,100,660 at December 31, 2013); no shares issued or outstanding, pro forma	44,928,382	44,928,382	
Series C, 12% non-cumulative, convertible preferred stock, $.0001 par value, authorized 2,711,734 shares; issued and outstanding 1,578,400 shares in 2012 and	22,862,367	22,862,367	

2013 (liquidation preference of $23,676,000 at December 31, 2013); no shares issued or outstanding, pro forma		
Stockholders' deficit:		
Common stock, $.0001 par value, authorized 12,000,000 shares; issued 32,358 shares and outstanding 28,227 shares in 2012 and issued 78,086 shares and outstanding 73,954 shares in 2013; shares issued and outstanding, pro forma	83	88
Additional paid-in capital	45,385,265	46,872,723
Deficit accumulated during the development stage	(103,993,763)	(118,314,383)
Total stockholders' deficit	(58,608,415)	(71,441,572)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 27,518,140	$ 14,405,136 $

See accompanying notes.

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Statements of Operations

	Year Ended December 31		Period From December 22, 1997 (Inception) to December 31, 2013
	2012	2013	
Operating expenses:			
Research and development	$ 17,386,961	$ 9,154,484	$ 86,217,608
General and administrative	5,929,890	3,573,893	26,343,979
Total operating expenses	23,316,851	12,728,377	(112,561,587)
Loss from operations	(23,316,851)	(12,728,377)	(112,561,587)
Other income (expense)			
Interest expense	(140,051)	(1,512,911)	(1,677,370)
Interest income	25,762	1,658	1,599,051
Change in fair value of warrants	171,013	(80,990)	108,520
Other			(295,543)
Loss before benefit from income taxes	(23,260,127)	(14,320,620)	(112,826,929)
Benefit from income taxes			672,648
Net loss	(23,260,127)	(14,320,620)	(112,154,281)
Accretion of interest on shares subject to mandatory redemption			(5,560,102)
Beneficial conversion charge	(600,000)		(600,000)
Net loss attributable to common stockholders	$ (23,860,127)	$ (14,320,620)	$ (118,314,383)
Net loss per share (basic and diluted)	$ (845.29)	$ (405.14)	
Weighted-average shares outstanding (basic and diluted)	28,227	35,347	
		$	

Pro forma net loss per share applicable to common stockholders basic and diluted (unaudited)	
Weighted-average number of common shares used in pro forma net loss per share applicable to common stockholders basic and diluted (unaudited)	

See accompanying notes.

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Statements of Convertible Preferred Stock and Changes in Stockholders' Deficit
Period From December 22, 1997 (Inception) to December 31, 2013

	Pre-recapitalization					Post-recapitalization									
	Series A Convertible Preferred Stock		E-1 Convertible Preferred Stock		Common Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock	Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Notes Receivable	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Net Stockholders' Equity (Deficit)
Issuance of Series A convertible preferred stock	1,850,000	$ 1,850,000		$	$	$	$	$	$	$	$	$	$	$	$	$	$	$
Issuance of common stock to founders			1,085,000	109														109
Issuance of common stock upon exercise of options			150,000	15												9,985		10,000
Issuance of stock options in exchange for research and development services																19,168		19,168
Subscription receivable				(19)														(19)
Net loss for the period December 22, 1997 (inception) to December 31, 1997																	(55,153)	(55,153)
Balance, December 31, 1997	1,850,000	1,850,000	1,235,000	105												29,153	(55,153)	(25,895)
Issuance of Series B convertible preferred stock	256,945	1,027,780																
Issuance of common stock upon exercise of options			50,000	5												4,995		5,000
Subscription receivable				19														19
Issuance of stock options in exchange for research and development services																824		824
Net loss for the year ended December 31, 1998																	(1,881,168)	(1,881,168)
Balance, December 31, 1998	2,106,945	2,877,780	1,285,000	129												34,972	(1,936,321)	(1,901,220)
Issuance of Series B convertible preferred stock	125,000	500,000																
Issuance of common stock in exchange for a license, patent and technology			125,718	12												50,274		50,286
																	(1,294,654)	(1,294,654)

Net loss for the year ended December 31, 1999								
Balance, December 31, 1999	2,231,945	3,377,780	1,410,718	141		85,246	(3,230,975)	(3,145,588)
Issuance of stock options in exchange for research and development services						55,034		55,034
Net loss for the year ended December 31, 2000							(1,274,990)	(1,274,990)
Balance, December 31, 2000	2,231,945	3,377,780	1,410,718	141		140,280	(4,505,965)	(4,365,544)

See accompanying notes.

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Statements of Convertible Preferred Stock and Changes in Stockholders' Deficit (Continued)
Period From December 22, 1997 (Inception) to December 31, 2013

	Pre-recapitalization				Post-recapitalization								
	Series A Convertible Preferred Stock		E-1 Convertible Preferred Stock		Common Stock		Series A1 Convertible Preferred Stock	Series A2 Convertible Preferred Stock	Series B Convertible Preferred Stock	Series C Convertible Preferred Stock	Common Stock			
	Number of Shares	Amount	Number of Shares	Amount	Notes Receivable	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Net Stockholders' Equity (Deficit)
Balance, December 31, 2000 *(from previous page)*	2,231,945	$ 3,377,780	1,410,718	$ 141	$	$	$	$	$	$	$	$	$	$ 140,280	$ (4,505,965)	$ (4,365,544)
Issuance of Series C convertible preferred stock	4,132,689	11,158,260														
Issuance of common stock upon exercise of options			29,285	3										19,911		19,914
Issuance of stock options in exchange for research and development services														56,777		56,777
Net loss for the year ended December 31, 2001															(3,817,375)	(3,817,375)
Balance, December 31, 2001	6,364,634	14,536,040	1,440,003	144										216,968	(8,323,340)	(8,106,228)
Net loss for the year ended December 31, 2002															(5,084,053)	(5,084,053)
Balance, December 31, 2002	6,364,634	14,536,040	1,440,003	144										216,968	(13,407,393)	(13,190,281)
Issuance of common stock upon exercise of options			735,000	74										174,276		174,350
Issuance of stock options in exchange for research and development services														38,837		38,837
Net loss for the year ended December 31, 2003															(2,040,358)	(2,040,358)
Balance, December 31, 2003	6,364,634	14,536,040	2,175,003	218										430,081	(15,447,751)	(15,017,452)
Issuance of Series D convertible preferred stock	15,910,555	4,932,272														
Issuance of stock options in exchange for research and development services														45,419		45,419
Net loss for the year ended December 31, 2004															(1,580,891)	(1,580,891)
Balance, December 31, 2004	22,275,189	19,468,312	2,175,003	218										475,500	(17,028,642)	(16,552,924)
Issuance of common stock upon exercise of options						1,190,684	119							47,508		47,627
Issuance of common stock						80,645	8							24,992		25,000
Net loss for the year ended December 31, 2005															(2,251,526)	(2,251,526)

Balance, December 31, 2005	22,275,189	19,468,312	3,446,332	345		548,000	(19,280,168)	(18,731,823)

See accompanying notes.

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Agile Therapeutics, Inc.
(A Development Stage Enterprise)

Statements of Convertible Preferred Stock and Changes in Stockholders' Deficit (Continued)
Period From December 22, 1997 (Inception) to December 31, 2013

	Pre-recapitalization				Post-recapitalization								
	Series A Convertible Preferred Stock		E-1 Convertible Preferred Stock		Common Stock		Series A-1 Convertible Preferred Stock	Series A-2 Convertible Preferred Stock	Series B Convertible Preferred Stock	Series C Convertible Preferred Stock	Common Stock			
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Notes Receivable	Number of Shares	Number of Shares	Number of Shares	Number of Shares	Number of Shares	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Net Stockholders' Equity (Deficit)
Balance, December 31, 2005 *(from previous page)*	22,275,189	$ 19,468,312	3,446,332	$ 345	$	$	$	$	$	$	$	$	$ 548,000	$ (19,280,168)	$ (18,731,823)
Issuance of common stock for employee bonuses					180,216	18							7,191		7,209
Issuance of common stock in exchange for services					38,000	4									