

AGILE THERAPEUTICS INC
Form 424B4
May 23, 2014

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Filed pursuant to Rule 424(b)(4)
Registration No. 333-194621

PROSPECTUS

9,166,667 Shares

COMMON STOCK

We are offering 9,166,667 shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. The initial public offering price is \$6.00 per share.

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "AGRX."

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

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

	Per Share	Total
Initial public offering price	\$ 6.00	\$ 55,000,002
Underwriting discount and commissions(1)	\$ 0.42	\$ 3,850,000
Proceeds, before expenses, to us	\$ 5.58	\$ 51,150,002

(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 1,375,000 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 \$4,427,500 and the total proceeds to us, before expenses, will be \$58,822,502.

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Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$25.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed 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 May 29, 2014.

RBC CAPITAL MARKETS

WILLIAM BLAIR

CANTOR FITZGERALD & CO.

JANNEY MONTGOMERY SCOTT

Prospectus dated May 22, 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 June 16, 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 hormone, 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 \$117.5 million as of March 31, 2014.

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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	9,166,667 shares
Common stock to be outstanding immediately after this offering	18,592,059 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 1,375,000 additional shares of common stock.
Use of proceeds	<p>The net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$49.2 million.</p> <p>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.</p>
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.
NASDAQ Global Market symbol	AGRX

The number of shares of our common stock that will be outstanding immediately after this offering includes 113,519 shares of common stock outstanding as of March 31, 2014, 8,809,317 shares of common stock issuable upon conversion of all currently outstanding shares of our convertible preferred stock and 502,556 shares of common stock issuable upon conversion of all currently outstanding convertible subordinated promissory notes upon the completion of this offering. This calculation excludes:

any shares of common stock issuable upon exercise of the over-allotment option granted to the underwriters;

1,387,291 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014 at a weighted average exercise price of \$4.19 per share;

35,003 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2014, at an exercise price of \$10.71 per share; and

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867,759 shares of common stock available for future grant under our 2014 Incentive Compensation Plan, or the 2014 Plan, which will become effective on the date of this offering (including the shares of common stock reserved for issuance under our 2008 Equity Incentive Plan, which shares will be added to the shares reserved under the 2014 Plan upon its effectiveness), as of March 31, 2014.

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

an amendment and restatement of our charter and bylaws upon the closing of this offering;

the expiration without exercise of all outstanding warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock;

the conversion, on a 1.4-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 35,003 shares of common stock upon the closing of this offering;

the conversion of the aggregate principal amount of \$3.0 million and interest accrued as of May 21, 2014 under our outstanding convertible subordinated promissory notes into 502,556 shares of common stock upon the closing of the offering at the initial public offering price of \$6.00. For a description of the convertible subordinated promissory notes, see "Management's Discussion and Analysis of Financial Condition and Results of Operations April 2014 Convertible Subordinated Note Financing;" and

a 1.4-for-one stock split of our common stock effected on May 7, 2014.

Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$25.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares in 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. We have derived the statements of operations data for the three months ended March 31, 2013 and 2014 and the balance sheet data as of March 31, 2014 from our unaudited financial statements included in this prospectus. The unaudited financial data include, in the opinion of management, all adjustments, consisting of normal recurring adjustments, that are necessary for a fair statement of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of the results to be expected for a full fiscal year. The following summary financial data should be read in conjunction with "Management's Discussion

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

	Years ended December 31,		Three Months Ended March 31,		Period from Inception (December 22, 1997) to March 31, 2014
	2012	2013	2013	2014	
(In thousands, except share and per share data)					
Statement of operations data:					
Operating expenses:					
Research and development	\$ 17,387	\$ 9,154	\$ 3,072	\$ 1,394	\$ 87,612
General and administrative	5,930	3,574	1,156	1,053	27,397
Total operating expenses	23,317	12,728	4,228	2,447	115,009
Loss from operations	(23,317)	(12,728)	(4,228)	(2,447)	(115,009)
Total other income (expense)	57	(1,592)	(377)	(366)	(631)
Loss before benefit for income taxes	(23,260)	(14,320)	(4,605)	(2,813)	(115,640)
Benefit from income taxes				3,652	4,325
Net loss	(23,260)	(14,320)	(4,605)	839	(111,315)
Beneficial conversion charge	(600)				(6,160)
Net (loss) income available to common shareholders	\$ (23,860)	\$ (14,320)	\$ (4,605)	\$ 839	\$ (117,475)
Weighted average basic common shares outstanding	39,518	49,486	42,181	106,309	
Weighted average diluted common shares outstanding	39,518	49,486	42,181	822,178	

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(Loss) income per common share basic(1)	\$	(603.78)	\$	(289.39)	\$	(109.18)	\$	0.10
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(Loss) income per common share diluted(1)	\$	(603.78)	\$	(289.39)	\$	(109.18)	\$	0.01
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(1) See Note 2 to our interim financial statements appearing at the end of this prospectus regarding the calculation of net income per share.

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	As of March 31, 2014		
	Actual	Pro Forma(1)	Pro Forma as Adjusted(2)
	(In thousands)		
Balance sheet data:			
Cash and cash equivalents	\$ 3,010	\$ 6,010	\$ 55,160
Total assets	15,992	18,992	68,142
Total current liabilities	7,897	7,265	7,265
Long term debt, less current portion	9,156	9,156	9,156
Convertible preferred stock	69,233		
Deficit accumulated during the development stage	(117,475)	(117,490)	(117,490)
Total shareholders' equity (deficit)	(70,294)	2,570	51,720

- (1) Pro forma amounts reflect (i) the expiration without exercise of all outstanding warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock, (ii) the conversion of all outstanding warrants to purchase shares of Series C convertible preferred stock into warrants to purchase 35,003 shares of common stock, (iii) the conversion of all our outstanding shares of convertible preferred stock into an aggregate of 8,809,317 shares of our common stock (iv) the sale of our convertible subordinated promissory notes on April 28, 2014 and (v) the conversion of all principal and interest accrued as of May 21, 2014 under our outstanding convertible subordinated promissory notes into an aggregate of 502,556 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 9,166,667 shares of our common stock in this offering at the initial public offering price of \$6.00 per share, and after deducting the 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.

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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. We recorded net income of \$0.8 million for the three months ended March 31, 2014 as a result of the proceeds received from the sale of a portion of our New Jersey state net operating losses. As of March 31, 2014, we had a deficit accumulated during the development stage of \$117.5 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

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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 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 \$3.0 million as of March 31, 2014. 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 March 31, 2014, 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 July 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 August 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

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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 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 March 31, 2014, we have cumulative net cash flows used by operating activities of \$105.9 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;

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Cash requirements of any future acquisitions or the development of other product candidates;

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

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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 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;

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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.

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

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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 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.

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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 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.

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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.

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;

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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;

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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.

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 payors or we may provide incentives to consumers covered by non-governmental payors, 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 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 CHCs, we cannot predict whether the FDA will require that we include information in the Twirla

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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 as any increased pricing pressure that those entities face from their customers, including the U.S.

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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 maintained by religious employers. However, the contraceptive mandate has remained

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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 and will stay in effect through 2024 unless additional Congressional action is taken. 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 tracing on 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, 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.

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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 May 20, 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 \$2.0 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 our common stock has been approved for listing on the 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 adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

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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 93.0% of our voting stock and, upon consummation of this offering, that same group will together hold approximately 67.0% 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, assuming \$25 million of shares are purchased in this offering by our existing stockholders, at the initial public offering price of \$6.00 per share.

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 March 31, 2014, and including the effect of the conversion of our convertible preferred stock, the net exercise of outstanding warrants to purchase shares of convertible preferred stock and the subsequent conversion of such preferred stock into shares of our common stock and the conversion of outstanding convertible subordinated promissory notes into shares of our common stock, upon the completion of this offering, we will have outstanding 18,592,059 shares of common stock, assuming no exercise of outstanding options. Of these shares, assuming \$25 million of shares are purchased in this offering by our existing stockholders at the initial public offering price of \$6.00 per share, 5,000,000 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 March 31, 2014 and including the effect of the conversion of our convertible preferred stock and the conversion of outstanding convertible subordinated promissory notes into shares of our common stock, an additional 13,592,059 shares will be eligible for sale in the public market. In addition, the 1,387,291 shares subject to outstanding options under our stock option plans and the 867,759 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 8,809,317 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 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

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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 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

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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 begins 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 \$3.27 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price of \$6.00 per share. In the past, we have issued options to acquire common stock at prices below the initial public offering price. To the extent any outstanding options are ultimately exercised, you will sustain further dilution.

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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 9,166,667 shares of our common stock that we are offering will be approximately \$49.2 million, based on the initial public offering price of \$6.00 per share and after deducting the 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 \$56.8 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 \$2 to \$4 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's Discussion and Analysis of Financial Condition and Results of Operations - 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.

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 March 31, 2014:

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 8,809,317 shares of our common stock, (ii) the expiration without exercise in connection with the closing of this offering of warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock, (iii) the automatic conversion of all outstanding warrants to purchase shares of Series C convertible preferred stock into warrants to purchase 35,003 shares of common stock, (iv) the sale of our convertible subordinated promissory notes on April 28, 2014 and (v) the conversion of all outstanding principal and interest accrued as of May 21, 2014 under our outstanding convertible subordinated promissory notes into an aggregate of 502,556 shares of our common stock; and

on a pro forma as adjusted basis to also reflect the sale of 9,166,667 shares of common stock by us in this offering at the initial public offering price of \$6.00 per share.

Each day after May 21, 2014, our outstanding convertible subordinated promissory notes will accrue approximately \$667 of additional interest, in the aggregate. To calculate the number of additional shares of common stock that we will issue upon conversion of the convertible subordinated promissory notes in connection with this offering, take the product obtained by multiplying the daily interest accrual amount by the number of days beginning on May 22, 2014 and continuing through to the closing of this offering and divide that result by the initial public offering price.

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 March 31, 2014		
	Actual	Pro Forma (In thousands) (Unaudited)	Pro Forma As Adjusted
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, 119,304 shares issued and 113,519 shares outstanding, actual; 25,000,000 shares authorized, 9,425,392 shares issued and outstanding pro forma; and 150,000,000 shares authorized, 18,592,059 shares issued and outstanding pro forma as adjusted	1	1	1
Additional paid-in capital	47,181	120,060	169,209
Deficit accumulated during the development stage	(117,475)	(117,490)	(117,490)
Total stockholders' (deficit) equity	(70,294)	2,570	51,720
Total capitalization	\$ (1,061)	\$ 2,570	\$ 51,720

The preceding table excludes:

1,387,291 of common stock issuable upon exercise of stock options outstanding as of March 31, 2014 at a weighted average exercise price of \$4.19 per share;

35,003 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2014 at an exercise price of \$10.71 per share; and

867,759 shares of common stock available for future grant under our 2014 Incentive Compensation Plan, or the 2014 Plan, which will become effective on the date of this offering (including the shares of common stock reserved for issuance under our 2008 Equity Incentive Plan, which shares will be added to the shares reserved under the 2014 Plan upon its effectiveness), as of March 31, 2014.

Table of Contents**DILUTION**

The historical net tangible book value of our common stock as of March 31, 2014 was \$(71.2) million, or \$(627.21) per share, based on the number of shares of common stock outstanding as of March 31, 2014. 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 March 31, 2014, we had a pro forma net tangible book value of \$1.7 million or \$0.18 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 8,809,317 shares of common stock underlying all outstanding preferred stock, including the Series C convertible preferred stock, Series B convertible preferred stock, Series A-1 convertible preferred stock and Series A-2 convertible preferred stock issued as of March 31, 2014 and including the conversion of all outstanding principal and interest accrued as of May 21, 2014 under our outstanding convertible subordinated promissory notes into an aggregate of 502,556 shares of our common stock. After giving effect to the issuance of 9,166,667 shares of common stock offered hereby at the initial public offering price of \$6.00 per share, and after deducting the underwriting discounts and commissions and our estimated offering expenses, our pro forma net tangible book value as adjusted as of March 31, 2014, will be approximately \$50.8 million, or approximately \$2.73 per pro forma share of common stock. This represents an immediate increase in pro forma net tangible book value of \$2.55 per share to our existing stockholders and an immediate dilution of \$3.27 per share to new investors in this offering. The following table illustrates this per share dilution:

Initial public offering price per share		\$	6.00
Historical net tangible book value per share	\$	(627.21)	
Increase attributable to the conversion of the convertible preferred stock		627.39	
Pro forma net tangible book value per share before this offering		0.18	
Increase per share attributable to new investors		2.55	
Pro forma net tangible book value per share after this offering			2.73
Dilution per share to new investors		\$	3.27

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.

The following table summarizes, on a pro forma basis as of March 31, 2014, the difference between existing stockholders and the new investors participating in this offering at the initial public offering price of \$6.00 per share with respect to the number of shares of common stock purchased, the total consideration paid and the average price per share paid.

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percent %	Amount	Percent %	
Existing stockholders	9,425,392	51%	\$ 106,375,000	66%	\$ 11.29
New Investors	9,166,667	49	55,000,002	34	6.00
Total	18,592,059	100%	\$ 161,375,002	100%	\$ 8.68

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The share data in the table above is based on shares outstanding as of March 31, 2014, 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 March 31, 2014, and excludes:

1,387,291 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014 at a weighted average exercise price of \$4.19 per share;

35,003 shares of common stock available upon the exercise of outstanding warrants as of March 31, 2014 at an exercise price of \$10.71 per share; and

867,759 shares of common stock available for future grant under our 2014 Incentive Compensation Plan, or the 2014 Plan, which will become effective on the date of this offering (including the shares of common stock reserved for issuance under our 2008 Equity Incentive Plan, which shares will be added to the shares reserved under the 2014 Plan upon its effectiveness), as of March 31, 2014.

If the underwriters' over-allotment option is exercised in full, the shares held by existing stockholders will decrease to 47% 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 10,541,667, or 53%, of the total number of shares of common stock outstanding after this offering.

Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$25.0 million of shares of our common stock in this offering at the initial public offering price. At the initial public offering price of \$6.00 per share, these entities would purchase an aggregate of 4,166,667 of the 9,166,667 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these existing stockholders or their affiliated entities.

Table of Contents**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 balance sheet data as of December 31, 2012 and 2013 from our audited financial statements, included elsewhere in this prospectus. We have derived the statements of operations data for the three months ended March 31, 2013 and 2014 and the balance sheet data as of March 31, 2014 from our unaudited financial statements included in this prospectus. The unaudited financial data include, in the opinion of management, all adjustments, consisting of normal recurring adjustments, that are necessary for a fair statement of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of the results to be expected for a full fiscal year.

	Years ended December 31,		Three months ended March 31,		Period from Inception (December 22, 1997) to March 31, 2014
	2012	2013	2013	2014	
(In thousands, except share and per share data)					
Statement of operations data:					
Operating expenses:					
Research and development	\$ 17,387	\$ 9,154	3,072	\$ 1,394	\$ 87,612
General and administrative	5,930	3,574	1,156	1,053	27,397
Total operating expenses	23,317	12,728	4,228	2,447	115,009
Loss from operations	(23,317)	(12,728)	(4,228)	(2,447)	(115,009)
Total other income (expense)	57	(1,592)	(377)	(366)	(631)
Loss before benefit for income taxes	(23,260)	(14,320)	(4,605)	(2,813)	(115,640)
Benefit from income taxes				3,652	4,325
Net loss	(23,260)	(14,320)	(4,605)	839	(111,315)
Beneficial conversion charge	(600)				(6,160)
Net loss available to common shareholders	\$ (23,860)	\$ (14,320)	\$ (4,605)	\$ 839	\$ (117,475)
Weighted average basic common shares outstanding	39,518	49,486	42,181	106,309	

Weighted average diluted common shares outstanding	39,518	49,486	42,181	822,178
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(Loss) income per common share basic(1)	\$ (603.78)	\$ (289.39)	\$ (109.18)	\$ 0.10
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(Loss) income per common share diluted(1)	\$ (603.78)	\$ (289.39)	\$ (109.18)	\$ 0.01
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(1) See Note 2 to our interim financial statements appearing at the end of this prospectus regarding the calculation of net income per share.

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	As of December 31,		As of
	2012	2013	March 31,
	2014		
	(In thousands)		
Balance sheet data:			
Cash and cash equivalents	\$ 20,014	\$ 2,120	\$ 3,010
Total assets	27,518	14,405	15,992
Total current liabilities	2,107	6,844	7,897
Long term debt, less current portion	14,787	9,770	9,156
Convertible preferred stock	69,233	69,233	69,233
Deficit accumulated during the development stage	(103,994)	(118,314)	(117,475)
Total shareholders' deficit	\$ (58,608)	\$ (71,442)	\$ (70,294)

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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, \$9.2 million and \$1.4 million during the years ended December 31, 2012 and 2013 and the three months ended March 31, 2014, 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 March 31, 2014, we had received net proceeds of approximately \$121.1 million from such equity and debt sales and such term loan. As of December 31, 2012, December 31, 2013 and March 31, 2014 respectively, we had \$20.0 million, \$2.1 million and \$3.0 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 March 31, 2014, our losses from operations have been \$115.0 million. Our net loss was \$23.9 million and \$14.3 million for the years ended December 31, 2012 and 2013, respectively. We recorded net income of \$0.8 million for the three months ended March 31, 2014 as a result of the proceeds received from the sale of a portion of our New Jersey state net operating losses. 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

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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 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

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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.

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. For the three months ended March 31, 2013 and 2014 our research and development expenses were approximately \$3.1 million and \$1.4 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		Three months ended March 31,	
	2012	2013	2013	2014
	(In thousands)			
Clinical development	\$ 2,337	\$ 693	\$ 241	\$ 68
Regulatory	3,326	2,686	839	133
Personnel related	1,837	1,783	471	471
Manufacturing commercialization	7,496	2,290	905	385
Manufacturing	2,042	840	324	210
Stock-based compensation	349	862	292	127
Total research and development expenses	\$ 17,387	\$ 9,154	\$ 3,072	\$ 1,394

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.

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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.

For the years ended December 31, 2012 and 2013, our general and administrative expenses totaled approximately \$5.9 million and \$3.6 million, respectively. For the three months ended March 31, 2013 and 2014, our general and administrative expenses totaled approximately \$1.2 million and \$1.1 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 c