AGILE THERAPEUTICS INC
Form 10-K
March 26, 2015

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Item 8. Financial Statements and Supplementary Data

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the year ended December 31, 2014

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**23-2936302**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

101 Poor Farm Road
Princeton, New Jersey 08540
(Address including zip code of principal executive offices)

(609) 683-1880
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

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

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2014 was approximately $78.7 million.

As of March 16, 2015 there were 22,154,365 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2014, are incorporated by reference in Part II and Part III of this Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K

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Agile Therapeutics, Inc.
Annual Report on Form 10-K
For The Year Ended December 31, 2014

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development of Twirla and our other product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials;
- our inability to timely obtain from our third party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial;
- our ability along with Corium to complete successfully the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- our ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans to develop and commercialize our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- our available cash;

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- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the performance of third-party manufacturers; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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Item 1. Business

Overview

We are a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. We have developed a proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and stability and patient comfort. Our lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. The U.S. hormonal contraceptive market, with total market sales of $5.3 billion in 2014, represents the greatest opportunity for Twirla. Over half of those sales were generated by branded products. Currently, there is only one other contraceptive patch available in the United States which is available in branded and generic versions, and we believe it has limitations due to its dose and physical characteristics. Twirla is designed to address these limitations. We believe there is an unmet market need for a low-dose contraceptive patch, which is designed to increase patient convenience and compliance in a non-invasive fashion.

Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives. Twirla is designed using our proprietary Skinfusion technology to consistently deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives. By delivering these active ingredients over seven days, in a comfortable, convenient and easy-to-use weekly patch, Twirla is designed to promote enhanced patient compliance. The patch is applied once weekly for three weeks, followed by a week without a patch. If approved, Twirla will be packaged with three patches per carton to provide for one 28-day cycle of therapy.

We have conducted a comprehensive clinical program, with completed Phase 1, Phase 2, and Phase 3 trials enrolling over 2,100 women, over 1,500 of whom received Twirla. We are currently conducting an additional Phase 3 trial, the SECURE study, in which we plan to enroll approximately 2,100 women for up to one year of treatment. 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. In our completed Phase 3 trials to date, 485 women received Twirla for 12 months. Across all completed clinical trials, Twirla was generally well tolerated and had a favorable safety profile.

We have filed a Section 505(b)(2) New Drug Application, or NDA, for approval of Twirla by the U.S. Food and Drug Administration, or FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relies in part on clinical trials that we conducted and in part on the FDA's findings of safety and efficacy from investigations for approved products containing the active ingredients and published scientific literature for which we have not obtained a right of reference. The FDA has indicated in a Complete Response Letter, or CRL, that our NDA was not sufficient for approval as originally submitted. After multiple communications with the FDA, we have received significant guidance as to what additional clinical development and other activities need to be completed prior to approval. In accordance with the FDA's advice and comments, we are conducting an additional Phase 3 clinical trial which was initiated in 2014 and is currently enrolling subjects. Based on the guidance that we received from the FDA, we believe that this additional trial will address all of the

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

We intend to commercialize Twirla in the United States, if approved, through a direct sales force. Obstetricians and gynecologists, or ObGyns, contribute nearly 45% of the U.S. contraception prescription volume, and Nurse Practitioners and Physician Assistants, or NP/PAs, who are often affiliated with an ObGyn practice, contribute an additional 25% 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 we expect 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 seven 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.

Background

Hormonal Contraception Overview

A woman is biologically capable of pregnancy from the time of her first menstrual cycle, at the average age of 12.6 years, to natural menopause, at the average age of 51.3 years. This is nearly half of

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a typical woman's lifespan and, for the typical woman, the majority of this time frame is spent trying to avoid pregnancy or is characterized by no desire to become pregnant. Nearly half of the pregnancies that occur each year in the United States are unplanned. The United States was the first country to approve a hormonal contraceptive, with the approval of the first contraceptive pill in 1960. The latest data from 2011 to 2013 from the Centers for Disease Control, or CDC, indicate that approximately 28% of women aged 15 to 44 use some form of hormonal contraception, which amounts to approximately 17 million U.S. women.

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

Hormonal contraceptives are generally well-tolerated and are generally safer than pregnancy. A risk associated with hormonal contraceptives is a rare but serious adverse event called venous thromboembolism, or VTE, which involves the formation of a blood clot in a vein. VTEs can be life-threatening, and typically present as either deep vein thrombosis or pulmonary embolism. Evidence supports that the increased risk of VTE in CHC users is dependent upon the estrogen dose and duration of use. Estrogen increases formation of clotting factors in the liver and decreases production of elements that promote breakdown of blood clots. Most experts believe that progestins on their own have minimal to no impact on the clotting system, but some progestins, when combined with estrogen, can increase estrogen's effect on the clotting system.

The likelihood of a woman spontaneously developing a VTE is extremely low and the use of combination oral contraceptives, or COCs, increases the incidence only slightly, and less than pregnancy. Epidemiologic studies evaluated by the FDA have demonstrated the incidence of VTE in women based on pregnancy or use of COCs as follows:

Incidence of VTE Based on Pregnancy Status or use of COCs

Population	VTE incidence (cases per 10,000 woman years*)
Non-pregnant woman who does not use a COC	1 to 5
COC users	3 to 12
Pregnant women	5 to 20
Postpartum women (in the 12 weeks following delivery)	40 to 65

*

One woman year is one woman using a contraceptive for one year, which is either 12 months or 13 cycles

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

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containing third and fourth generation progestins are associated with an increased risk of VTE as compared to those containing the second generation progestin, LNG.

Effectiveness of Hormonal Contraceptives

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

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

U.S. Hormonal Contraceptive Market Background

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

- oral contraceptive;
- vaginal ring;
- transdermal patch;
- intrauterine contraceptive device, or IUD;
- subcutaneous implant; and
- injectable.

The U.S. hormonal contraceptive market recorded annual sales in 2014 of $5.3 billion, according to IMS Health. The CHC portion of the market, consisting of pills, a transdermal patch and a vaginal ring, generates significantly greater prescription volume and sales compared to the P-only portion of the market, consisting of IUDs, injectables, implants, and P-only pills. In 2014, IMS Health reported total U.S. sales of $4.0 billion for the CHC market and $1.3 billion for the P-only market. Twirla is a CHC and, if approved, we believe it will compete primarily with products in the CHC market.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. In the past 10 years, the market growth was flat to declining as measured by prescription volume, with the exception of a 4.8% increase in 2013 compared to 2012. The average annual growth rate in dollar sales for the five years ended December 31, 2014 was 2.9% for the total hormonal contraceptive market and 0.7% for the CHC market. Market growth in gross sales is primarily due to price increases amongst branded products.

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

Contraceptive Population
(Total women aged 15-44 yrs)

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

Second, in 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or collectively, the ACA, was signed into law, which, among other things, requires all health plans, with limited exceptions, to cover certain preventive services for women with no cost sharing, which means no deductible, no co-insurance and no co-payments by the patient, effective August 1, 2012. These services include those set forth in the Guidelines for Women's Preventive Services, or HRSA Guidelines, and adopted by the U.S. Department of Health and Human Services Health Resources and Services Administration. Contraceptive methods and counseling, including all FDA approved contraceptive methods as prescribed, are included in the HRSA Guidelines. Since these new ACA provisions went into effect in August 2012, quarterly prescription volume growth for the CHC market rose from negative growth year-on-year to positive growth between 4.0% and 5.0% for each of the six quarters following implementation. However, this appears to be a temporary phenomenon, as the market volume growth in 2014 fell to 0.8%, a rate closer to population growth.

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Effect of the ACA on CHC Market Growth

Source: IMS National Prescription Audit, IMS Health

During the period following enactment of the ACA, generic oral contraceptives have shown the greatest growth, primarily at the expense of branded oral contraceptives. This is likely due to the policies that have been implemented by many managed care plans, which are generally only providing generic oral contraceptives with no cost-sharing to the patient. The effect on non-oral products is less clear, but prescription volume for the vaginal ring showed a 5.9% decline from 2013 to 2014, while the prescription volume for the patch increased by 2.1% over the same time period. As interpreted by the applicable governmental agencies, health plans are only required to cover one product for each contraceptive "method" without cost-sharing by the patient. For other products that fall within the same "method" that are not the preferred product, payors are allowed to use reasonable medical management techniques, such as applying cost-sharing obligations. We therefore cannot be sure that the growth in the CHC market is due entirely to the new coverage and ACA requirements, and it is too early to determine the full effect of the ACA on our business. We believe the CHC market will maintain a long-term positive annual growth rate in line with contraceptive population growth.

In spite of the availability of generic contraceptives for over 25 years, branded products have maintained a significant share of the CHC market, with 58% of dollar sales and 22% of prescriptions for the 12 months ended September 2014. Branded contraceptives in the CHC market have driven significant increases in the value of branded total prescriptions, or TRx. In the five years ended December 2014, the average annual price increase among the top branded products was 10.4%. The average price per cycle, referred to as the wholesale acquisition cost, or WAC, for a single 28-day cycle of the top branded products was $41.53 in 2006 and rose to $108.61 by January 2015. The branded and generic forms of the CHC transdermal patch are currently priced at $110.22 and $95.12 per cycle, respectively. The other non-oral form of CHC, the vaginal ring, is currently priced at $105.81 per cycle. We cannot predict whether the manufacturers of branded products will continue to increase prices going forward, but we believe we will be able to set a WAC price for Twirla, if approved, that is comparable to other branded CHC products at the time of launch. Based on IMS Health data, we estimate that each percentage point of market share of CHC total prescriptions in the United States currently represents approximately $136 million of annual gross sales potential for Twirla, if approved.

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Contraceptive Pills

Based on data from the CDC, of women who choose to use a hormonal contraceptive, approximately 64% use the contraceptive pill, vaginal ring or patch, the majority of which use the contraceptive pill. We believe that contraceptive pills are the most popular choice because:

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

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

Contraceptive Patch Market Experience

The Ortho Evra® contraceptive patch, or Evra, was introduced in early 2002 and was the first FDA-approved contraceptive patch. The initial approved labeling for Evra indicated that it delivered a daily EE dose of 20 micrograms. Evra had rapid uptake in the contraceptive market, and achieved a 10% share of the CHC market by September 2003. Following FDA approval of Evra, users of Evra began to report thrombotic and thromboembolic events to the FDA. Johnson & Johnson, the manufacturer of Evra, revised the Evra labeling in November 2005 to include information that EE exposure with Evra is 60% higher than that of an oral contraceptive containing EE of 35 micrograms, based on area under the curve, a commonly-used metric for measuring EE exposure in contraceptives. This information was ultimately included in a black box warning and bolded warnings unique to the Evra label. The Evra market share declined rapidly following the labeling changes, from a peak share of 11% in 2005, to 4% by the end of 2006, to 1.4% by the end of 2013, where it appears to have stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent in 2014.

In April 2014, Mylan Inc. announced the launch of Xulane , a generic version of Evra. Generic pharmaceutical products are the chemical and pharmaceutical equivalents of the brand or a reference listed drug, or RLD. Generic drugs are bioequivalent to their reference brand name counterparts. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the RLD product containing the same active ingredients. Bioavailability is a measure of the rate and extent to which the active ingredient is absorbed from a drug product and becomes available at the site of action. Under pharmacy dispensing rules governed by state law, depending on the state, if an automatic generic substitute is introduced, the pharmacist may dispense either the prescribed product, or they may replace it with an equivalent generic without being required to inform the patient or healthcare professional. In addition, the FDA offers a 180-day exclusivity period for generic products in specific cases. The first generic applicants to submit a substantially complete Abbreviated New Drug Application containing a paragraph IV certification to a listed patent are protected from competition from other generic versions of the same drug for the 180 days. As of March 2015, no other generic equivalents to Evra have been introduced.

The FDA has maintained, in spite of the wording in the labeling for Evra and its approved generic, that none of the epidemiologic studies to date provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased

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risk that some studies demonstrated is directly attributable to Evra. An advisory committee for the FDA stated that the benefits of Evra outweigh the risks. In its denial of a Citizen's Petition calling for the withdrawal of Evra, the FDA followed the committee's recommendations stating that the increased VTE risk does not warrant removal from the market, and that the labeling revisions to the Evra label provide an update and guidance on the interpretation of the epidemiologic data about the risk of VTE with Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, Evra and its generic equivalent generated $153 million in gross sales in 2014.

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

Our Product Candidates

Each of our product candidates utilizes our proprietary Skinfusion technology, which is designed to provide advantages over the currently available patch. Skinfusion is designed to deliver contraceptive-levels of hormones to the blood stream through the skin over a seven-day period. It is also designed to optimize patch adherence and stability and patient comfort. Our lead product candidate is Twirla, a prescription CHC patch which contains both EE and LNG and is designed to deliver a low dose of EE and LNG comparable to the total dose delivered with low-dose oral contraceptives. In addition to Twirla, we are developing a pipeline of other new transdermal contraceptive products, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle and AG200-SP, which is a regimen designed to provide shorter, lighter monthly withdrawal bleeding. We are also developing AG890, which is a P-only prescription contraceptive patch intended for use by women who are unable or unwilling to take estrogen.

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

Agile Therapeutics Pipeline

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Twirla Product Overview

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

Twirla is designed to be highly appealing to patients as a method of contraception. The patch is round and made of a soft, flexible, silky fabric, designed to flex with the movement of a woman's body. Twirla is a matrix patch consisting of several layers of material that contain the active ingredients EE and LNG, as well as the inactive ingredients Dimethylsulfoxide, Ethyl Lactate, Capric Acid and Lauryl Lactate, which are ingredients to assist in the transport of EE and LNG across the skin, and adhesives that enable adherence to the skin. The final top layer is the one seen on the skin, and consists of a thin, silky material consisting of only adhesive. There is a barrier formed between the inner portion of the patch, which contains the active ingredients, and the outer portion of the patch, which only contains the adhesive. This barrier is intended to prevent the active and inactive ingredients from migrating to the peripheral portion of the patch, and from breaking down the adhesive in that portion of the patch. Twirla is also designed to help prevent seepage of the adhesives from around the edge of the patch where it could collect dirt and leave a sticky black ring on the skin. The six layers of the patch are integrated to create a patch which has a slim profile, and is unobtrusive when applied. The results of

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multiple clinical trials suggest that Twirla delivers the active ingredients needed for contraception over a seven-day period and that it remains adhered to the skin of most subjects for the full seven-day period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.

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Twirla Patch Profile

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

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

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

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

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

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Twirla **Evra**

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

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

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EE Concentrations (pg/ml)

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

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

Twirla Product Profile

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

- Twirla is a weekly contraceptive patch, designed to offer convenience and compliance.
- Twirla is designed to meet the contraceptive needs and the busy lifestyle of today's women.
- Twirla contains the active ingredients EE and LNG, both of which have been used in contraceptives for over 25 years.
- Twirla delivers the low daily dose of EE of approximately 30 micrograms, comparable to low-dose oral contraceptives.

Twirla is designed to demonstrate efficacy comparable to other approved prescription contraceptives.

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Twirla has a favorable safety and tolerability profile.

Twirla was designed with Skinfusion technology, which has demonstrated adhesion over the seven-day wear period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.

Because Twirla contains the progestin LNG, we believe that the final approved label for Twirla will be consistent with the class labeling for other contraceptives containing EE and LNG, including the class black box warning.

Twirla Clinical Development Program

Completed Clinical Trials

Our clinical program includes three Phase 1 studies, one Phase 2 study, and three Phase 3 studies, as well as other supporting studies. We are currently conducting the third Phase 3 study in response to FDA comments and guidance. In Phase 1 and Phase 2 clinical trials, we demonstrated that Twirla delivers levels of both EE and LNG to the blood stream that are consistent with currently marketed low-dose oral contraceptives. In our completed Phase 3 clinical trials, we demonstrated that Twirla was comparable to an approved low-dose oral contraceptive in two randomized studies, one that enrolled over 1,500 women over 12 months and the other that enrolled over 400 women over six months. Across all completed clinical trials, Twirla was generally well-tolerated and had a favorable safety profile. Because we relied, in part, on the FDA's findings of safety and efficacy from investigations for approved products containing EE and LNG and published scientific literature for which we have not obtained a right of reference, we were not required to conduct preclinical studies. In the pharmacokinetic study comparing Twirla to an approved low-dose oral contraceptive, results demonstrated that Twirla delivers a daily dose of EE that results in estrogen exposure similar to low-dose oral contraceptives containing approximately 30 micrograms.

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

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

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blood clots, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease and hypertension, and a black box warning regarding risks of smoking and CHC use and particularly in women over 35 years old that smoke.

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

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

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

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

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

Study Population Demographics in Selected Contraception Trials

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

*

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

Current user definitions (extrapolated for approved products):

(a)

Used a hormonal contraceptive within 7 days of enrollment.

(b)

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

(c)

Using oral contraceptives prior to study start.

Use within 6 months of enrollment definitions:

(d)

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

(e)

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

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Twirla Pearl Indices Stratified By New Users and Minority Subjects

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

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

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

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

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

CRL and FDA Interactions

In February 2013, we received a CRL from the FDA indicating that the results from our completed Phase 3 trials would not be sufficient for approval, and the FDA proposed that we conduct an additional Phase 3 trial. Among the comments expressed in the letter were some regarding the PI values seen in the studies. Specifically, the FDA indicated that the PI values in the studies, in both the subjects using the Twirla patch and the control arm using oral contraceptives, were higher than seen in clinical trials used for registration of other approved hormonal contraceptives. The FDA recommended that we conduct an additional Phase 3 trial with a simplified clinical trial design and improved study conduct, including site monitoring and data collection procedures. The FDA also required additional information relating to the laser etching of label information on each patch and required that the patch used in the new trial utilize the same etching as will be used for the commercial product, in order to demonstrate that it does not adversely affect the performance of the patch. Furthermore, the FDA also requested in the CRL additional information on controls and release specifications related to the patch, and manufacturing and control information related to the Drug Master File of one of the raw materials in Twirla.

In October 2013, we met with the FDA and received further guidance on requirements for our planned Phase 3 trial. In addition, we had a follow-up written interaction with the FDA in February 2014 and have received substantial written comments from the FDA in subsequent interactions. We enrolled the first subject in the SECURE study in the third quarter of 2014, and expect to complete enrollment in the third quarter of 2015. The patches being studied in the SECURE study are laser etched using the same process as we anticipate for commercialization of Twirla, if approved. We will continue additional supportive testing in order to respond to the FDA's CMC questions.

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The SECURE study, our third Phase 3 Clinical Trial

Our third Phase 3 clinical trial is intended to address a number of issues identified in the CRL, including but not limited to, a simplified trial design, study conduct, recruitment of study population and compliance. We have designed the SECURE study as follows:

- Single-arm study;
- Approximately 2,100 female subjects will receive Twirla for up to one year;
- Approximately 80 sites located in the United States with experience in conducting contraceptive studies;
- The subjects are using 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 and adhesion; and
- We will assess patch adhesion based on a quantifiable daily subject assessment of percent adherence of the patch to the skin.

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

The SECURE study is employing several measures designed to improve upon one aspect of prior study conduct: loss to follow-up. First, the SECURE study is being conducted in approximately 80 sites in the United States that have experience conducting contraceptive trials and experienced study coordinators. Study sites have been evaluated extensively for their prior hormonal birth control trial experience through a data-driven approach assessing performance on previous clinical studies, staffing of experienced study coordinators with longevity at the site, demographics of potential study subjects, and audit history. Fewer sites will enable more focused oversight of participating sites and facilitate more individualized attention to enrolled study subjects, as compared to our previous Phase 3 study which was conducted at 96 sites. Training of study coordinators at the investigator meeting, at study initiation visits, and through ongoing communication should also reduce loss to follow-up. In addition, study sites that are showing early trends toward higher rates of loss to follow-up or overall poor study management will be re-trained and, if necessary, discontinued. Upon subject enrollment, sites will also ask for multiple methods of contact for each subject, and will obtain permission to contact family members and utilize public records to locate subjects who are lost to follow-up.

After site selection, recruitment of the study population is the next crucial step toward achievement of a population that will provide reliable and generalizable data in the SECURE study. We have trained our sites to provide individualized attention to recruitment of subjects who are most likely to adhere to the study protocol with respect to compliance, including correct patch application, timing of patch removal and replacement, electronic diary, or e-diary, completion and study visits. Potential subjects are carefully screened for ability, motivation and willingness to comply with all of the study visits and other requirements. Study coordinators and investigators have received in-depth training on selection of appropriate subjects prior to beginning subject enrollment, and these criteria are being reviewed throughout the study enrollment period. Subjects are also advised through the informed consent process that noncompliance with study procedures may lead to discontinuation from

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the trial. In addition, each site is providing real-time recruitment information to the CRO throughout the recruitment process, which facilitates enrollment of the appropriate subject population. We continue to expect that enrollment of the SECURE study will be completed in the third quarter of 2015.

A number of measures have been put in place in order to facilitate compliance with study procedures. To ensure subjects are adequately educated regarding their responsibilities during the trial, a detailed subject teaching plan has been developed and implemented, and subject education regarding the importance of compliance, including videos, brochures and one-to-one education with study coordinators, is provided at repeated intervals throughout the study. A number of measures have been put in place to support and monitor compliance through the study. One key measure is the use of e-diary and text message technology, which provides personalized reminders to subjects for patch application, diary completion and study visits, measures we believe will improve overall subject compliance. Phone contact with subjects between visits is part of the study protocol, which will increase the frequency of contact with subjects throughout the study.

The electronic diary platform being utilized in the SECURE study is PHT's LogPad® system, a handheld device specifically designed for subject-entered data capture. In addition to contributing to improved compliance, the use of e-diary technology may also contribute to improved data quality and completeness in the SECURE study. Subjects use their e-diaries to record the data that are critical to the calculation of the PI, including sexual activity and use of back-up contraception. Subjects also record their bleeding patterns and patch adherence using a new, more precise scale. During the study screening period, subjects receive comprehensive training on use of the e-diaries and are required to demonstrate both appropriate use and ability to comply with the study protocol during a two-week run-in period in order to be enrolled in the study. The diaries are designed to be simple and easy-to-use, and to enhance data quality, and have built-in prompts to avoid subject error in data entry. As the subjects enter data into the e-diaries, information is transmitted to the vendor database and is available for real-time review by the Agile team, the CRO and our study monitors. The CRO and our study monitors analyze individual subject and site data and can immediately implement additional training or intervention with study site coordinators and subjects as needed, including potentially discontinuing noncompliant sites or subjects. Real-time e-diary and study visit data also potentially minimize the number of subjects lost to follow-up. By selecting an appropriate subject population and implementing the compliance measures described above, we anticipate that the number of pregnancies will be reduced as compared to the previous Phase 3 studies. None of these real-time measures were utilized in our previous clinical trials. We believe we have designed and are implementing a clinical trial that addresses the feedback provided by the FDA in the CRL and additional guidance we have received in subsequent interactions with the FDA.

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

The observed PI values will not only be impacted by the number of pregnancies that occur in the study, but also by the number of cycles that are included in the analysis, which affects the denominator of the PI calculation. Cycles in which a subject is not sexually active, has incomplete diary information or uses a back-up method of contraception will not be counted toward the number of cycles included in

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the calculation of the PI. Indicators of subjects who are likely to exhibit the behaviors listed above are being carefully assessed during the recruitment process so as to reduce the number of cycles discarded from the analysis.

We have engaged Parexel International Corporation, or Parexel, a CRO with substantial experience in contraception studies and excellent site monitoring capabilities. We actively participated in site selection, and actively participate in monitoring subject recruitment, site monitoring and oversight of Parexel's activities, and will continue to do so throughout the length of the trial. Our CRO was selected based not only on the above criteria, but on a clear track record of responding to trends and information through early intervention in order to assure compliance with trial procedures at both the subject and site levels.

Assuming successful completion of the SECURE study by the second half of 2016, we plan to submit a complete response that includes the additional clinical trial results to the FDA in the first half of 2017.

Twirla Line Extensions and Other Product Candidates

In addition to Twirla, our product pipeline consists of two classes of product candidates: Twirla line extensions and other transdermal contraceptive product candidates. These product candidates are designed to address market needs and offer additional non-daily contraceptive options. Based on the results of our market research on line extension regimen concepts, we believe that our line extension product candidates are commercially viable and could garner a share of the contraceptive market.

The hormonal contraceptive market has a long history of manufacturers successfully using line extensions to extend the lifecycle of a brand, often by gaining additional exclusivity periods for the product extension under the provisions of the Hatch-Waxman Act or with additional patents. Our lifecycle strategy with Twirla is to introduce line extensions that will have exclusivity for some time period, either due to our intellectual property estate, or due to Hatch-Waxman exclusivity. The line extensions in our pipeline include using our Skinfusion technology to allow a 28-day regimen where women will experience shorter, lighter withdrawal bleeding, as well as extending the cycle beyond the typical 28-day regimen to allow women to experience fewer withdrawal bleeds each year.

Our Twirla line extensions include the following:

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

AG200-SP is a 28-day regimen designed to provide users with shorter, lighter withdrawal bleeds and potentially improve contraceptive efficacy. AG200-SP may also provide benefit in patients with sensitivity to abrupt changes in hormone levels. Oral contraceptives that use a shortened hormone-free interval, or SHFI, by delivering hormones beyond 21 days currently comprise 43% of U.S. branded TRx volume, demonstrating high acceptability among patients and providers. AG200-SP is designed to provide a simplified 28-day regimen through use of a smaller, lower-dose patch in the fourth week, which will allow patients to continuously apply patches

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without interruption. AG200-SP requires additional patch development work prior to potentially conducting Phase 1 studies.

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

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

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

Sales and Marketing

Twirla Commercialization Strategy

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

Twirla Promotion Strategy

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

Seeking advice and input from key opinion leaders, or KOLs, in women's health and contraception;

Sponsoring continuing medical education, or CME, programs at key congresses and symposia around the country;

Establishing relationships with women's health advocacy groups;

Conducting extensive market research to better understand the market dynamics and identify product positioning and messages for Twirla with prescribers and consumers;

Assuring that data from our clinical trials are presented in a timely manner at clinical congresses and published in appropriate peer-reviewed medical journals; and

Developing and registering the trademark Twirla and developing key branding elements, including packaging design for submission with the NDA.

Prescribing in the CHC category is primarily driven by ObGyns, who write nearly 45% of the total prescriptions. In addition, NPs and PAs, who are often affiliated with an ObGyn practice but can also

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

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

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

Market Research

We have conducted market research with healthcare professionals, consumers and managed care decision-makers to determine market drivers, unmet needs and the reaction to the Twirla product profile. A total of nearly 650 healthcare professionals and over 3,000 consumers have participated in our market research on Twirla and the contraceptive market. The main findings of the market research are discussed below.

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Topline Summary of Our ObGyn/NP Market Research:

- Compliance is a substantial problem with oral contraceptives, and many women are not comfortable with the "invasiveness" of a vaginal ring, IUD or implant.
- The daily dose of estrogen delivered is the most important information requested by ObGyns and NPs in order for them to prescribe Twirla, if approved.
- Prescribers need assurance that what happened with Evra will not occur with Twirla, although they are generally unable to state the actual EE dose delivered by Evra.
- ObGyns are not familiar with the PI calculation, and generally assume all FDA-approved contraceptives are about equally effective.

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

Topline Summary of Our Consumer Market Research:

- The most important benefit to consumers is the ability for Twirla to "make their life easier" and "take birth control off their minds."
- All women are "busy" and most women admit to missing at least one or more birth control pills every month.
- There is little to no awareness of Evra among consumers, and no pre-existing safety hangover to overcome.
- The fact that Twirla may minimize the 'black ring' effect is important.
- Among women who are currently considering starting prescription contraception, nearly half would be interested in using Twirla, and over 90% of those interested said they would discuss Twirla with their doctor.

Topline Summary of Our Managed Care Market Research:

- Contraceptives are not among the top categories affecting health plan budgets. New contraceptives will likely be subject to 'hands off' management by payors.
- Prior to formulary review, most commercial plans will add Twirla, if approved, to their system and reimburse the product as a non-preferred agent.

Contracting is a critical driver to gain preferred formulary placement.

The managed care research summarized above was conducted prior to the implementation of the contraceptive mandate in the ACA. We have reviewed the latest policies released in 2014 for several major managed care plans and these reveal that the various plans have interpreted the requirement for coverage of contraceptives under the ACA differently. Some plans have designated that all contraceptives containing the same progestin are equivalent, and therefore only cover a select few products containing each progestin, usually the least expensive generics, with no co-pay. Other plans

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have defined contraceptive methods into categories such as "hormonal", "emergency contraception", and "barrier methods", and they cover just one product for each method with no co-pay. Generally, it appears that most plans are only offering generic oral contraceptives at a zero co-pay and that branded or non-oral CHC products are often available only with cost-sharing by the patient, usually in the form of a Tier 3 co-pay, or at no cost with prior authorization from the prescriber. IUDs and implants can usually be obtained at no cost to the patient only if they are purchased by the physician, rather than by the patient at a pharmacy.

Competition

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

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

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

Although there are over 180 CHC products, including branded and generics, available on the market today, approximately 50% of the total market sales, or $2.1 billion in 2014, consisted of sales of just eight branded products. Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The product with the highest dollar sales in the CHC market for the 12 months ending December 2014 was Nuvaring®, marketed by Merck, the only contraceptive vaginal ring available on the market, with over $650 million in sales for 2014. The Loestrin® franchise, marketed by Allergan (formerly known as Actavis), consisting of two oral contraceptives, Minastrin® 24 and LoLoestrin®, also totaled over $550 million in sales in 2014. Other competing products include: Gianvi® and Quartette®, marketed by Teva, Beyaz® and Yaz®, which totaled over $160 million in sales in 2014, and Mirena®, marketed by Bayer, Generess®, which had over $110 million in sales in 2014, marketed by Allergan, and Alesse®, marketed by Pfizer. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal and Mylan. Ortho Tri-Cyclen® Lo, also an oral contraceptive, had $480 million in sales in 2014, in spite of no promotion by Johnson & Johnson. Ortho Evra® achieved $150 million in sales in 2013, but faced competition from a generic version introduced in April 2014 by Mylan called Xulane ®. Xulane captured $77 million in sales in 2014, but the total combined patch sales of Evra plus Xulane were $153 million. Based on the market experience of other non-oral dosage forms, including the Evra product, we believe there is a continuing demand for an

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innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are other contraceptive products in development that, if approved, will compete with Twirla and our other product candidates. Companies that have new contraceptive products in various stages of development include Bayer's contraceptive patch and an oral contraceptive, each in Phase 3 development and Teva's oral contraceptive in Phase 3 development. Allergan has a vaginal ring which is a generic equivalent to Nuvaring and an IUD that is similar to Mirena awaiting approval, a P-only patch for which they received a CRL from the FDA, and an oral contraceptive and an additional vaginal ring in Phase 2 development. However, in the past few years, some of the large pharmaceutical companies such as Johnson & Johnson and Pfizer have dissolved their women's health specialty marketing and sales teams, and Bayer has shifted their focus away from their CHC products to their IUD franchise.

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

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

Manufacturing

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

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the current Phase 3 clinical trial (the SECURE study) needs. Corium needs to conduct the equipment and facility validation and expansion of its manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla, if approved. We expect the validation and expansion to be completed in coordination with our planned commercialization activities. Corium is responsible for all aspects of Twirla manufacturing.

Strategic Agreements

Agreement with Corium

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

Under our agreement, Corium has performed process development and manufacturing of Twirla for each of our clinical trials. For the development work performed, we paid Corium for time and materials related to the achievement of certain development goals. To date, we have made approximately $1.7 million of milestone payments to Corium, all of which were paid between the years 2006 and 2009. Corium is not eligible for any milestone payments in the future. During 2012, we paid Corium an aggregate of $3.5 million towards leasehold improvements incurred by Corium to its facilities to provide for adequate manufacturing space for our product candidates.

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

Reimbursement

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

Managed care plans have individually interpreted the requirement for coverage of contraceptives under the ACA. Some plans have designated that all contraceptives containing the same progestin are equivalent, and therefore only cover a select few products containing each progestin, usually the least expensive generics, with no co-pay. Other plans have defined contraceptive methods into categories such as "hormonal", "emergency contraception", and "barrier methods", and they cover just one product for each method with no co-pay. Generally, it appears that most plans are only offering generic oral contraceptives at a zero co-pay and that branded or non-oral CHC products are often available

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only with cost-sharing to the patient, usually in the form of a Tier 3 co-pay, or at no cost with prior authorization from the prescriber. IUDs and implants can usually be obtained at no cost to the patient only if they are purchased by the physician, rather than by the patient at a pharmacy.

Government Regulation

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

FDA Regulation

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

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

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

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

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

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

Submission to the FDA of an NDA;

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

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

FDA review and approval of the NDA.

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Preclinical Studies and IND Submission

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND, unless the sponsor is relying on prior FDA findings of safety or efficacy of the drug product, in which case, some of the above information may be omitted. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

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

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

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution.

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Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur. Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website. Marketing application applicants must also report certain investigator financial interests to FDA.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

U.S. Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be filed at the time of the first submission of the application, even if the application is being submitted on a rolling basis. A user fee for the Twirla contraceptive patch was submitted with the original NDA. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application. The FDA's standard review goal is to act on 90% of all Non-New Molecular Entity applications within ten months of FDA receipt of the application. This time period may be extended by FDA should an applicant submit new information to the agency during the course of FDA's review of the marketing application. The time period is also only a goal and may not be met by FDA. We expect that our products, if and when approved, will be subject to a standard review goal.

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

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted

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application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held, as well as the manufacturing processes and controls, meet standards designed to ensure the product's continued safety, quality and purity.

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

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

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

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

Even if the FDA approves a product candidate, it may limit the approved indications for use of the product candidate and require that contraindications, warnings or precautions be included in the product labeling, including a black box warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Moreover, the FDA may require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS could materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements, FDA notification, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

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Hatch-Waxman Act

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

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

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

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period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

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

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

Our NDA for Twirla was submitted under Section 505(b)(2), and we expect that some of our other drug candidates will utilize the Section 505(b)(2) regulatory pathway. Even though several of our drug products utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and efficacy of those active ingredients in the formulation and dosage forms that we are developing. All approved products, both innovator and generic, are listed in the FDA's Orange Book.

U.S. Post-Approval Requirements

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

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documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

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

- Restrictions on the marketing, distribution or manufacturing of the product, complete withdrawal of the product from the market or requests for product recalls;
- Fines, or Untitled, Cyber or Warning Letters or holds on or termination of post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties including disgorgement, restitution, fines and imprisonment;
- Consent decrees, corporate integrity agreements or exclusion from federal healthcare programs;
- Debarment;
- Mandated modification of promotional materials and labeling and the issuance of corrective information; or
- The FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product.

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

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

Moreover, the recently enacted Drug Quality and Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the

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

U.S. Fraud and Abuse, Data Privacy and Security and Transparency Laws and Regulations

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

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

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

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper promotion of off-label uses not expressly approved by the FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. Additionally, the civil monetary penalties statute, which, among other things, imposes fines against any person who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also

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created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payor.

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

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

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

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to a variety of penalties, depending upon the law found to have been violated, potentially including criminal and significant civil monetary penalties,

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

Coverage and Reimbursement Generally

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

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products, including pharmaceuticals. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to

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enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Healthcare Reform

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

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

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

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates if they are approved.

The Foreign Corrupt Practices Act

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

Foreign Regulation

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

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Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $13.4 million, $9.2 million, and $17.4 million for the years ended December 31, 2014, 2013, and 2012, respectively. We plan to increase our research and development expenses for the foreseeable future as we continue our ongoing Phase 3 clinical trial for Twirla and subsequently advance the development of our other product candidates.

Intellectual Property

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

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

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

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

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

Because patent applications in the United States and certain other jurisdictions generally are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of our entitlement to patent rights in the inventions covered in our issued patents and pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, USPTO, to determine priority of invention, or in post-grant challenge proceedings in the USPTO or

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foreign patent offices such as oppositions, reexamination, inter-partes review, post grant review, or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

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

In both our Twirla product candidate line and in AG890, the active adhesive system consists of the active ingredients in a polyacrylate adhesive polymer matrix comprising the permeation enhancers dimethylsulfoxide, ethyl lactate, capric acid and lauryl lactate. The active blend is coated onto a release liner, and a backing layer is added on top of the active blend. The peripheral adhesive system, also called the overlay, comprising three layers is added onto the backing layer. The overlay comprises a polyisobutylene adhesive layer, an acrylic adhesive layer, and an overlay covering. The overlay covering is a commercially available silk-like polyester fabric. The adhesive components of the overlay, in addition to their adhesive function, create an *in situ seal* with the disposable release liner, trapping evaporable solvents in the active blend, thereby extending the usable shelf life of the product candidate and contributing to the comfort and effectiveness of the transdermal system during use. Prior to use of any of our product candidates, the release liner is removed by the user and discarded. The patch is then applied to the skin.

Seven U.S. patents, issuing from three patent families, have been or are being submitted to the FDA for listing in the Orange Book upon approval of Twirla. These patents include claims directed to transdermal delivery systems having an active adhesive matrix and claims directed to methods of controlling fertility by applying such transdermal delivery systems, and in all cases including a skin permeation enhancer. One of our seven issued U.S. patents will expire November 22, 2020. Four will expire March 14, 2021. A fifth patent will expire July 10, 2028. The sixth will expire August 26, 2028.

U.S. Patent No. 7,045,145 is directed to the wet formulation of the transdermal delivery system used in Twirla, prior to drying, and expires in March 2021; product-by-process claims cover patches manufactured by drying wet formulations of the active adhesive matrix. U.S. Patent No. 7,384,650, U.S. Patent No. 8,221,784, and U.S. Patent No. 8,221,785 are all directed to the dry final product formulation of the transdermal delivery system used in Twirla, and expires in March 2021. U.S. Patent No. 8,221,784 covers both Twirla and AG890. Foreign counterparts to these patents have been granted in Australia, Canada, China, Europe, India, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, Norway, the Philippines, South Africa and Taiwan and are pending in other countries. U.S. Patent No. 8,883,196 is directed to a method of controlling fertility by applying Twirla or AG890 once each week for three weeks followed by a one week rest interval and expires November 22, 2020.

U.S. Patent Nos. 8,246,978 and 8,747,888 are directed to structural features of the transdermal delivery system used in Twirla and AG890 patch design for transdermal delivery of hormones or of other drugs. As such, these patents protect a platform technology for delivery of LNG, EE, other hormones, and other drugs. These patents expire in August 2028 and July 2028, respectively. Foreign counterparts are issued in New Zealand and are pending elsewhere.

In addition, we own 53 issued patents in jurisdictions other than the United States, including patents in New Zealand, Australia, Canada, Austria, Belgium, Cyprus, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey, Indonesia, Israel, India, Japan, South Korea, Mexico, Norway, the Philippines, Taiwan and

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South Africa. These issued foreign patents include claims directed to transdermal delivery systems having an active adhesive matrix and claims directed to methods of controlling fertility by applying such transdermal delivery systems, and in all cases including a skin permeation enhancer. In addition, we have 55 pending patent applications in the United States and certain foreign jurisdictions for Twirla and AG890, and for unique patch dosage regimens intended to align with future label expansions and line extensions, such as AG200-ER and AG200-SP, including an anti-oxidant formulation and a desogestrel patch.

Regulatory Exclusivity

Our NDA for Twirla was submitted under Section 505(b)(2) of the Food, Drug, and Cosmetic Act, or FDCA. Even though Twirla utilizes API that were previously approved in the United States, Twirla utilizes LNG in a new dosage form, specifically a transdermal patch, and we provided new clinical data essential to approval in our NDA to establish the safety and efficacy of Twirla. Therefore, if approved by the FDA, we expect to receive three years of U.S. marketing exclusivity for Twirla. The exclusivity will prohibit the FDA from approving ANDAs and 505(b)(2) NDAs for the conditions of the Twirla approval. We will consider whether we are going to pursue patent term restoration, however, we do not expect to receive patent term restoration because, as explained above, Twirla will not be the first approval of the API.

Employees

As of December 31, 2014, we had 14 full time employees, including seven in research and development and seven in general and administrative roles. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced a work stoppage and consider our relations with our employees to be good.

Corporate Information

We were incorporated in Delaware in December 1997. Our offices are located at 101 Poor Farm Road, Princeton, New Jersey 08540, and our telephone number is (609) 683-1880.

Available Information

Our corporate website address is www.agiletherapeutics.com. Information contained on or accessible through our website are not a part of this annual report on Form 10-K, and the inclusion of our website address in this annual report is an inactive textual reference only. We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700 million as of the prior March 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below as well as the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. 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. In these circumstances, the market price of our common stock would likely decline.

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 are not currently pursuing any regulatory approvals for Twirla or any other product candidate outside the United States.

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 are conducting an additional Phase 3 clinical trial for Twirla®, which commenced 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 have received substantial written comments from the FDA in subsequent interactions, 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 ongoing 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, including whether our data are reliable and generalizable.

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 published scientific literature or the FDA's prior approval of 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

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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, if we seek foreign regulatory approval for Twirla or any of our other product candidates, we may not obtain such 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 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 ongoing 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,

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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. While our ongoing Phase 3 clinical trial was designed and is being implemented in a manner to address the FDA's comments and guidance, it is possible that the trial may not be successful or the FDA could conclude the data are not reliable or generalizable. 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, if utilized in our clinical trials, 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 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 ongoing 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

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experienced a high withdrawal rate in our two completed Phase 3 clinical trials for Twirla and to date, have experienced slower than anticipated enrollment in our current Phase 3 trial;

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;

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 are currently conducting a Phase 3 clinical trial for Twirla and we expect to conduct additional clinical trials in the future 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;

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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 completed 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;

Subject's relationship with her partner; and

Other events that may occur and are beyond our control.

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 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 our initial public 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;

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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;

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;

Our inability to validate our commercial manufacturing process;

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 be unable to obtain agreement from the FDA on product labeling;

We may have insufficient funds to pay the significant user fees required by the FDA upon the filing of any future NDAs; 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

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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 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;

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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 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 are currently conducting. 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 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

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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.

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 attributable to common stockholders were $16.1 million, $14.3 million and $23.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of $134.4 million.

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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 conduct our additional Phase 3 clinical trial for Twirla, respond to the CRL and supplement our NDA with the results of the trial, complete the qualification and validation of our commercial manufacturing process, advance our other product candidates and expand our research and development programs. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants. 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.

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. Our cash and cash equivalents were $40.2 million as of December 31, 2014. In January 2015, we completed a private placement where we raised approximately $19.3 million of net proceeds. In February 2015 we completed a debt refinancing which allowed us to repay our existing loan facility of approximately $15.5 million and also provides an additional tranche of $8.5 million subject to the achievement of certain clinical milestones. Based on our current operating plans, we believe that our cash and cash equivalents as of December 31, 2014, along with the net proceeds from our January 2015 private placement and the net proceeds and interest-only period associated with the first tranche of our debt facility completed in February 2015 will be sufficient to meet our anticipated operating needs through the end of 2016. 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 or we encounter any unforeseen events that affect our current business plan.

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

As of December 31, 2014, we had $15.0 million of principal indebtedness outstanding under our loan and security agreement with Oxford Finance LLC, or Oxford. In February 2015, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., or Hercules, for a term loan of up to $25.0 million. A first tranche of $16.5 million was funded upon execution of the loan agreement, approximately $15.5 million of which was used to repay our term loan with Oxford. Under terms of the loan agreement, we may, but are not obligated to, draw an additional tranche of up to

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$8.5 million prior to July 1, 2016, subject to the achievement of certain clinical milestones, which may be extended to December 31, 2016 under certain circumstances.

The Hercules 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 Hercules 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 June 2016. The term loan currently bears interest at rate of 9.0% per annum and matures on December 1, 2018.

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 Hercules loan agreement, an event of default will occur if, among other things, we fail to make payments under the loan agreement; we breach any of our covenants under the loan agreement, subject to specified cure periods with respect to certain breaches; Hercules 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 Hercules 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. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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

Our operations have consumed substantial amounts of cash since inception. From our inception to December 31, 2014, we have cumulative net cash flows used by operating activities of $121.3 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 ongoing, planned and potential future clinical trials;

- Time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;

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Our ability to successfully commercialize our product candidates, if approved;

Our ability to have commercial product successfully manufactured consistent with FDA regulations;

Amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;

Sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of expanding our marketing and sales capabilities;

Terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

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

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 our existing cash and cash equivalents as of December 31, 2014, along with the net proceeds from our January 2015 private placement and the net proceeds and interest-only period associated with the first tranche of our debt facility completed in February 2015, will be sufficient to fund our projected operating requirements through the end 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, complete validation of our commercial manufacturing process 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.

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

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

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Extent and strength of our third-party manufacturer and supplier support;

Extent and strength of our marketing and distribution support;

Limitations or warnings contained in our product's FDA approved labeling; and

Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan.

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 in the third quarter of 2016, we plan to submit a complete response to the FDA that will include additional clinical trial results and manufacturing information to our NDA in the first half of 2017. Assuming a six-month review by the FDA, we could receive a decision by the end of 2017. We intend to launch Twirla as soon as possible following receipt of approval from the FDA, if granted. However, we cannot assure you that the FDA will approve Twirla or that the FDA's timeline for review will be within six months. Following our original submission of the NDA, we received a CRL from the FDA requesting, among other things, additional Phase 3 data. Assuming timely and successful completion of this additional Phase 3 study and other

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items such as timely and successful completion of validation of equipment for commercial manufacturing, and ultimate FDA approval, we expect to be ready for the commercialization by the end of 2017.

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 the final submission to our NDA or establish our own sales force or engage a contract sales organization in the United States until shortly prior to FDA approval of Twirla. At the time of our anticipated commercial launch of Twirla, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Twirla in the United States.

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

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

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

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

To the extent that we rely on, or partner with, third parties to commercialize Twirla, if approved, or any other product candidate for which we obtain marketing approval in the future, we may receive less revenue than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. We, however, will remain responsible for the conduct of any contract sales force, which could expose us to legal and regulatory enforcement actions and liability. 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.

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

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

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

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

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

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

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;

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- The proportion of the contraceptive market comprised of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive;

- Competition in the contraceptive market could increase, with the introduction of new contraceptives, including the potential of a new generic or branded competitive contraceptive patch;

- Competition from generic contraceptive products could increase as additional generic contraceptives receive FDA approval;

- Implementation of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effect on pharmaceutical coverage, reimbursement and pricing could limit our revenue; and

- Access to the prescriber universe, particularly obstetrics and gynecology physicians, could be limited, decreasing our ability to promote Twirla efficiently.

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

- The level of contraceptive effectiveness of Twirla demonstrated in our clinical trials;

- The incidence and severity of adverse effects associated with Twirla;

- Limitations on use or warnings contained in FDA-approved labeling;

- Acceptability to patients of the appearance and feel of Twirla;

- Willingness of patients to try a new contraceptive and to use a transdermal patch as their form of contraception;

- Willingness of physicians to prescribe a contraceptive patch in light of safety issues and restrictive labeling of the currently marketed contraceptive patch;

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

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

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

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.

Moreover, we may face additional generic or other drug product competition sooner than we anticipate for Twirla or our other product candidates, which would potentially limit their commercial success. We believe that we may be eligible for three years of FDA marketing exclusivity for Twirla and our other product candidates. The FDCA provides a period of three years of marketing exclusivity for

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an NDA, Section 505(b)(2) NDA or supplement to an existing NDA for a drug product that contains a previously approved active moiety, if new clinical investigations, other than bioavailability or bioequivalence studies, were conducted or sponsored by the applicant and are determined by the FDA to be essential to the approval of the application. This three year marketing exclusivity, however, does not protect drug products from all competition. For instance, it does not protect against the approval of a full NDA. It also would only protect against the approval of a product that contains the same conditions of approval as our product candidates. We may not receive the three year exclusivity for any of our product candidates, and, even if we do, it may not adequately protect us from competition. Competition that our product candidates may face from generic or similar versions of our product candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

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 continues 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 December 2014, 78% of the prescription volume and 42% 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.

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.

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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 venous thromboembolism, or 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 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.

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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 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. 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

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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 controversial, with several legal challenges filed around the country, and the U.S. Supreme Court ruled in June 2014 that owners of certain private companies can object to the contraceptive mandate on religious grounds. 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

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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, 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

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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 imprisonment, refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution. If our contract manufacturer experiences issues in its manufacturing process or is unable to produce clinical supplies in adequate quantity and quality, our clinical trial could be delayed or our ability to receive regulatory approval of our product candidates could be negatively affected. Additionally, if there are changes to the manufacturing process for Twirla or to our formulation for Twirla that require a change in the manufacturing process, we could experience significant additional cost and our ability to receive regulatory approval could be delayed.

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 and while we obtain regulatory approval for the addition of a new manufacturer.

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

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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 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

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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 conducting 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 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.

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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. Distribution practices will also need to comply with the applicable regulatory requirements. If our distributors do not comply with the applicable regulatory requirements, we could be exposed to potential enforcement actions.

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, 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. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. 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

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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. 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 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

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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;

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.

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

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

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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 a variety of different consequences, depending upon which law we are found to have violated, including 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, 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

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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 patents that have been, or will be, 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;
- Our patents may face paragraph IV challenges from potential generic or 505(b)(2) applicants, asserting that our applicable patents are invalid, enforceable, or will not be infringed by the manufacture, use, or sale of the competitive drug product;
- 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;
- 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

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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.

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

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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.

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.

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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 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.

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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 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.

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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 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 proprietary

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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 identified 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.

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 March 16, 2015, we had a total of 14 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

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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 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

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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 $10.0 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.

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.

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

As a public company, we continue to 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. We estimate that we will annually incur approximately $2.0 million in expenses in response to these requirements.

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 our initial public 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 may 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

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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 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 have adopted a code of conduct, 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.

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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 our initial public 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 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 relating to our initial public offering, either on a standalone basis or when combined with future transactions, has caused 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. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained.

In May 2014, we closed our initial public offering. Prior to our initial public offering, there was no public market for shares of our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on The NASDAQ Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares.

We expect that our stock price may fluctuate significantly.

Prior to our initial public offering, you could not buy or sell our common stock publicly. The trading price of our common stock is highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this quarterly report, these factors include:

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 ongoing Phase 3 clinical trial for Twirla;

Our failure to commercialize Twirla, if approved, or develop and commercialize additional product candidates;

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Unanticipated efficacy, safety or tolerability concerns related to the use of Twirla;

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.

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

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.

As of March 16, 2015, we had 22,154,365 shares of common stock outstanding. Of these shares, 12,618,736 shares of common stock are freely tradeable, without restriction, in the public market.

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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

In addition, the 2,240,059 shares subject to outstanding options under our stock option plans and the 617,793 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.

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.

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.

As of December 31, 2014, our executive officers, directors, director nominees, holders of 5% or more of our capital stock and their respective affiliates together beneficially owned approximately 74.8% of our outstanding voting stock.

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.

We will have broad discretion in how we use the net proceeds from our initial public offering and our recently completed private placement. 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 from our recently completed initial public offering. We intend to use the majority of the net proceeds from our initial public offering and our recently completed private placement to conduct a Phase 3 clinical trial for Twirla, obtain marketing approval and begin preparations for the U.S. commercial launch of Twirla, continue the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities, develop our product pipeline, 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 from our recently completed initial public 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

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addition, pending their use, we may invest the net proceeds from our recently completed initial public 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 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 we completed our initial public 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.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to

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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.

We are 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.

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 relies 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 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;

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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 acquirers 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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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information and Holders of Record

Our common stock has been listed on the Nasdaq Global Market under the symbol "AGRX" since May 23, 2014. Prior to that date, there was no public trading market for our common stock. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	High	Low
Year Ended December 31, 2014		
Fourth Quarter	$ 7.52	$ 5.77
Third Quarter	$ 10.50	$ 5.80
Second Quarter (from May 23, 2014)	$ 12.55	$ 5.05

As of March 16, 2015, we had 48 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include shareholders whose shares may be held in trust by other entities. The closing price of our common stock on March 16, 2015 was $9.67.

Dividends

We have never declared or paid a cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board may deem relevant.

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Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Agile Therapeutics, Inc. under the Securities Act of 1933, as amended or the Exchange Act.

The following graph shows a comparison from May 23, 2014 (the date our common stock commenced trading of the Nasdaq Global Market) through December 31, 2014 of the cumulative total return for our common stock, and the NASDAQ Composite Index and The NASDAQ Biotechnology Index. The graph assumes that $100 was invested at the market close on May 23, 2014 in the common stock of Agile Therapeutics, Inc., the NASDAQ Composite Index and The NASDAQ Biotechnology Index and assumes reinvestments of dividends. The stock price performance of the following graph is not necessarily indicative of future stock price performance.

Comparison of 8 Month Cumulative Total Return
Assumes initial investment $100
December 31, 2014

	5/23/2014	6/30/2014	9/30/2014	12/31/2014
Agile Therapeutics, Inc.	$ 100.00	$ 157.40	$ 131.77	$ 110.83
NASDAQ Composite	$ 100.00	$ 105.31	$ 107.35	$ 113.15
NASDAQ Biotechnology	$ 100.00	$ 109.63	$ 116.68	$ 129.67

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds

On May 22, 2014, the Company's registration statement on Form S-1 (File No. 333-194621) for our IPO was declared effective by the Securities and Exchange Commission, or SEC. On May 29, 2014, we completed our IPO whereby we sold 9,166,667 shares of common stock, at a public offering price of $6.00 per share, before underwriting discounts and expenses. The aggregate net proceeds received by us

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from the offering were $49.7 million after deducting the underwriting discounts and commissions and offering expenses paid by us.

As of December 31, 2014, we have used approximately $9.5 million of our net proceeds from the IPO primarily to fund the Phase 3 clinical trial for Twirla and general working capital purposes.

There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated May 22, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, as revised in our Quarterly Report on Form 10-Q for the period ended June 30, 2014, filed with the SEC on August 14, 2014.

(c) Issuer Purchases of Equity Securities

None.

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Item 6. Selected Financial Data

The following table sets forth our selected financial data for the periods indicated. You should read the following selected financial data in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report.

The statement of operations data for the years ended December 31, 2014, 2013 and 2012, and the balance sheet data as of December 31, 2014, 2013 and 2012, are derived from our audited financial statements included elsewhere in this Annual Report. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		
	2014	2013	2012
	(In thousands, except share and per share amounts)		
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 13,365	$ 9,154	$ 17,387
General and administrative	5,150	3,574	5,930
Total operating expenses	18,515	12,728	23,317
Loss from operations	(18,515)	(12,728)	(23,317)
Other income (expense)			
Interest expense	(1,566)	(1,513)	(140)
Interest income	3	2	26
Change in fair value of warrants	348	(81)	171
Loss before benefit from income taxes	(19,730)	(14,320)	(23,260)
Benefit from income taxes	3,652		
Net loss	(16,077)	(14,320)	(23,260)
Beneficial conversion charge			(600)
Net loss attributable to common stockholders	$ (16,077)	$ (14,320)	$ (23,860)
Net loss per share (basic and diluted)	$ (1.41)	$ (289.39)	$ (603.78)
Weighted-average shares outstanding (basic and diluted)	11,394,971	49,486	39,518

	As of December 31,		
	2014	2013	2012
	(In thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 40,182	$ 2,120	$ 20,014
Working capital	31,993	(4,578)	18,161
Total assets	54,826	14,405	27,518

Accounts payable	2,631	715	1,127
Loan payable, long-term	9,828	9,770	14,787
Convertible preferred stock		69,233	69,233
Total stockholders' equity (deficit)	36,006	(71,442)	(58,608)

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, "Business" and Item 8, "Financial Statements and Supplementary Data." For information on risks and uncertainties related to our business that may make past performance not indicative of future results, or cause actual results to differ materially from any forward-looking statements, see "Special Note Regarding Forward-Looking Statements," and Part I, Item 1A, "Risk Factors." 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 $13.4 million, $9.2 million and $17.4 million during the years ended December 31, 2014, 2013 and 2012, 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. We have funded our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through a term loan and governments grants. As of December 31, 2014 and 2013, respectively, we had $40.2 million and $2.1 million in cash and cash equivalents.

On May 29, 2014, we completed our initial public offering whereby we sold 9,166,667 shares of common stock, at a public offering price of $6.00 per share, before underwriting discounts and expenses. The aggregate net proceeds received by us from the initial public offering were approximately $49.7 million.

We have not generated any revenue and have never been profitable for any year. Our net loss attributable to common stockholders was $16.1 million, $14.3 million and $23.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, Twirla and any other product candidates we advance to clinical development. We will continue to invest in the Corium facility, and incur significant expenses, in order to complete the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla, if approved. We continue to plan the process of scaling up the commercial manufacturing capabilities for Twirla with Corium and the associated costs and timelines. We expect the validation and expansion to be completed in coordination with our planned commercialization activities. Corium is responsible for all aspects of Twirla manufacturing. If we obtain regulatory approval for Twirla, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing and distribution functions. We enrolled the first subject in our Phase 3 clinical trial in the third quarter of 2014. We expect that we are likely to complete the trial in the third quarter of 2016. We believe the key drivers of the timing for completion are subject screening and enrollment, remaining site initiation and the timelines for clinical supply.

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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, and 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 for our product candidates;
- costs associated with research, development and regulatory activities; and
- costs associated with equipment scale-up required for commercial production.

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

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

To date, our research and development expenses have related primarily to the development of Twirla. For the years ended December 31, 2014, 2013 and 2012 our research and development expenses

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were approximately $13.4 million, $9.2 million and $17.4 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		
	2014	2013	2012
Clinical development	$ 7,916	$ 693	$ 2,337
Regulatory	300	2,686	3,326
Personnel related	1,942	1,783	1,837
Manufacturing commercialization	1,303	2,290	7,496
Manufacturing	1,287	840	2,042
Stock-based compensation	617	862	349
Total research and development expenses	$ 13,365	$ 9,154	$ 17,387

It is difficult to determine with any certainty the duration and completion costs of our currently ongoing, 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, or experience issues with our manufacturing capabilities we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, insurance 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, 2014, 2013 and 2012, our general and administrative expenses totaled approximately $5.2 million, $3.6 million and $5.9 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,

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which would result in an increase in payroll and other expenses, particularly with respect to the sales and marketing of our product candidates.

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 significant estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this annual report on Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

fees paid to CROs in connection with clinical studies;

fees paid to investigative sites in connection with clinical studies;

fees paid to vendors in connection with preclinical development activities; and

fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

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

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Warrant Liability

We account for detachable warrants with non-standard anti-dilution provisions (referred to as down round protection) to purchase convertible preferred stock (prior to our IPO) and common stock as liabilities, as they are freestanding derivative financial instruments. The warrants are recorded as liabilities at fair value, estimated using a Black-Scholes option pricing model, and are subject to re-adjustment at each balance sheet date, otherwise known as marked to market, with changes in the fair value of the warrants recorded in our statements of operations.

Beneficial Conversion

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

Stock-Based Compensation

We account for stock-based compensation under ASC, 718 "Accounting for Stock Based Compensation." All stock-based awards granted to nonemployees are accounted for at their fair value in accordance with ASC 718, and ASC 505, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be required requires us to develop estimates of fair values of stock options as of the grant date.

We account for stock-based compensation by measuring and recognizing expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

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Comparison of Years Ended December 31, 2014 and 2013

	Year ended December 31,		
	2014	2013	Change
	(In thousands)		
Operating expenses:			
Research and development	$ 13,365	$ 9,154	$ 4,211
General and administrative	5,150	3,574	1,576
Total operating expenses	18,515	12,728	5,787
Other income (expenses)			
Interest expense	(1,566)	(1,513)	(53)
Interest income	3	2	1
Change in fair value of warrants	348	(81)	429
Loss before income taxes	(19,730)	(14,320)	5,410
Income tax benefit	3,652		3,652
Net loss	$ (16,077)	$ (14,320)	$ (1,758)

Research and development expenses. Research and development expenses increased by $4.2 million, or 46%, from $9.2 million for the year ended December 31, 2013 to $13.4 million for the year ended December 31, 2014. This overall increase in research and development expenses was primarily due to the following:

an increase in clinical development expenses of $7.2 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase is primarily related to CRO costs associated with our Phase 3 clinical trial for Twirla;

a decrease in regulatory expenses of $2.4 million. This decrease is primarily related to a decrease in regulatory consulting fees. Regulatory consulting fees for 2013 include professional fees associated with the review and preparation of a response to the CRL that we received from the FDA in February 2013. Regulatory consulting fees for 2014 relate to the preparation of the protocol for our ongoing additional Phase 3 clinical trial for Twirla;

a decrease in manufacturing commercialization expenses of $1.0 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013. Payments for labor and materials decreased from approximately $1.4 million in 2013 to $0.2 million in 2014 as the construction of the facility was principally completed in the first half of 2013 and the delivery and installation of a majority of the commercial manufacturing equipment was principally completed during the first three quarters of 2013. This decrease was partially offset by an increase in idle and other facility charges of $0.3 million.

General and administrative expenses. General and administrative expenses increased by $1.6 million, or 44%, from $3.6 million for the year ended December 31, 2013 to $5.2 million for the year ended December 31, 2014. This increase in general and administrative expense was primarily due to the following:

an increase in professional fees (primarily legal and accounting) of $0.7 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013 primarily associated with becoming a public company; and

an increase in directors and officers insurance expense of $0.4 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013 attributed to becoming a public company.

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Interest expense. Interest expense is primarily attributable to our term loan with Oxford. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Oxford and the amortization of the deferred financing costs associated with the term loan.

Interest income. Interest income comprises interest income earned on cash and cash equivalents.

Change in fair value of warrants. Certain of our warrants to purchase our preferred stock (prior to the IPO) and common stock are recorded at fair value and are subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding charge or credit to earnings recorded within change in fair value of warrant liability. The fair value of the convertible preferred stock warrants (prior to the IPO) and warrants to purchase common stock with non-standard anti-dilution provisions are determined using the Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the underlying stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, credit spread and expected volatility of the price of the underlying stock. During the year ended December 31, 2014, the fair value of our warrant liability changed by $0.4 million compared to the year ended December 31, 2013 reflecting the expiration of the Series A-1 and Series A-2 preferred stock warrants of $0.5 million, offset, in part, by an increase in the value of the common stock warrants of $0.1 million primarily due to the change in the fair value of the underlying common stock.

Benefit from income taxes. Benefit from income taxes for the year ended December 31, 2014 represents the proceeds we received from the sale of New Jersey net operating losses, or NOLs, as part of the Technology and Business Tax Certificate Program sponsored by the New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused state NOLs are allowed to sell these NOLs to other companies. In February 2014, we completed the sale of New Jersey state NOLs totaling approximately $39.1 million and research and development credits totaling approximately $0.4 million for net proceeds of approximately $3.6 million. There was no comparable transaction during the year ended December 31, 2013.

Comparison of Years Ended December 31, 2013 and 2012

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

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

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

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

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

a decrease in regulatory expenses of $0.6 million. The regulatory expenses for 2012 include consulting and NDA preparation fees as well as our Prescription Drug User Fee Act, or PDUFA, filing fee of approximately $1.8 million. Regulatory expenses for 2013 reflect the decrease in NDA preparation consulting and filing fees, offset, in part, by increased legal fees associated with preparing a response to the CRL we received from the FDA; and

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

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

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

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

Change in fair value of warrants. Certain of the warrants to purchase our preferred stock are recorded at fair value and are subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding change recorded within the change in fair value of warrant liability. The fair value of the convertible preferred stock warrants is determined using the Black-Scholes option pricing model which incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the

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underlying stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, credit spread and expected volatility of the price of the underlying stock. During the year ended December 31, 2013, the fair value of our derivative liabilities changed by $0.2 million as a result of the value of our preferred stock warrant derivative liabilities increasing primarily due to the change in fair value of the underlying stock.

Net Operating Losses and Tax Carryforwards

As of December 31, 2014, we had approximately $123.3 million of federal and $82.1 million of state net operating loss carryforwards. We also potentially have federal and state research and development tax credits which would offset future taxable income. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. As of December 31, 2014, all of our net operating losses were fully offset by a valuation allowance.

Liquidity and Capital Resources

On May 29, 2014, we completed our initial public offering whereby we sold 9,166,667 shares of common stock, at a public offering price of $6.00 per share, before underwriting discounts and expenses. The aggregate net proceeds received by us from the offering were $49.7 million.

At December 31, 2014, we had cash and cash equivalents totaling $40.2 million. We invest our cash equivalents in highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Year ended December 31,		
	2014	2013	2012
	(In thousands)		
Cash used in operating activities	$ (14,503)	$ (13,019)	$ (22,968)
Cash used in investing activities	$ (96)	$ (4,945)	$ (6,693)
Cash provided by financing activities	$ 52,661	$ 70	$ 40,113
Net increase (decrease) in cash and cash equivalents	$ 38,062	$ (17,894)	$ 10,452

Operating Activities

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our primary product candidate Twirla was being developed. With the initiation of the Phase 3 clinical trial in 2014, clinical development expenses increased as compared to 2013. Net cash used in operating activities was $14.5 million for the year ended December 31, 2014 and consisted of a net loss of $16.1 million which was offset, in part, by non-cash stock based compensation expense of $1.4 million. Net cash used in operating activities was $13.0 million for the year ended December 31, 2013 and consisted primarily of a net loss of $14.3 million which was offset, in part, by non-cash stock based compensation expense of $1.3 million. The incremental increase in cash used in operations in 2014 is due primarily to the increased research and development expense in 2014 offset, in part, by the proceeds received from the sale of New Jersey NOLs in 2014. Net cash used in operating activities was $23.0 million for the year ended December 31,

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2012 and consisted primarily of a net loss of $23.3 million which was offset, in part, by non-cash stock based compensation expense of $0.7 million.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2014, 2013 and 2012 was $0.1 million, $4.9 million and $6.7 million, respectively. Cash used in investing activities for these years primarily represents the acquisition of equipment to be used in the commercialization of Twirla.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2014 was $52.7 million which included net proceeds of (i) $49.7 million received from our initial public offering of 9,166,667 shares of common stock and (ii) $3.0 million received from the issuance of convertible bridge notes. Net cash provided by financing activities was $70,000 for the year ended December 31, 2013 resulting from the exercise of stock options. Net cash provided by financing activities was $40.1 million for the year ended December 31, 2012 which included net proceeds of (i) $22.9 million from the issuance of 1,578,400 shares of our Series C preferred stock, (ii) of $14.8 million from a term loan and (iii) $2.5 million from the issuance of 253,999 shares of our Series B preferred stock.

Funding Requirements and Other Liquidity Matters

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

- seek marketing approval for Twirla;
- establish a sales and marketing infrastructure to commercialize Twirla in the United States, if approved;
- continue the equipment qualification and validation related to the expansion of Corium's manufacturing facility;
- seek to identify additional line extensions for Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We expect our existing cash and cash equivalents as of December 31, 2014, along with the net proceeds from our January 2015 private placement and the net proceeds and interest-only period associated with the first tranche of our debt facility completed in February 2015, will enable us to fund our operating expenses and capital expenditures requirements through the end of 2016. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of Twirla, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the costs and timing of completion and the outcome of the current Phase 3 trial for Twirla;
- the costs, timing and outcome of regulatory review of Twirla, including for the additional Phase 3 trial for Twirla;

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the costs of the equipment qualification and validation related to the expansion of Corium's manufacturing facility;

the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Twirla, if approved;

the revenue, if any, received from commercial sales of Twirla, if approved; and

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market Twirla that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2014 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Term loan	$ 17,639	$ 6,293	$ 11,346		
Operating lease	149	149			
Total	$ 17,788	$ 6,442	$ 11,346		

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

December 2012 Loan Agreement

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

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

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

In connection with the term loan, we issued to Oxford warrants to purchase 62,505 shares of common stock at $6.00 per share. These warrants are exercisable for seven years from the date of issuance.

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

In January 2014, we amended our loan agreement with Oxford whereby the interest-only period was extended for three months through April 2014. The interest-only period was extended for an additional three months through July 2014 as a result of the convertible note financing which we completed in April 2014 (see below).

The interest-only period was further extended for an additional six months through January 2015 and the maturity date of the loan was extended to July 1, 2017 as a result of the completion of our initial public offering. In connection with the amendment to the loan agreement we paid Oxford a total of $150,000.

In February 2015, we terminated and repaid all amounts outstanding under the loan agreement with Oxford.

April 2014 Convertible Subordinated Note Financing

On April 28, 2014, we and certain of our existing preferred stockholders, all of whom qualify as accredited institutional investors, entered into a Convertible Subordinated Note Purchase Agreement pursuant to which such holders agreed to loan us an aggregate of $3.0 million. We issued Convertible Promissory Notes, referred to herein as the Notes, to evidence our payment obligations with respect to the $3.0 million. The Notes had an interest rate of 8%, accruing daily and compounding annually. The Notes and accrued interest automatically converted into 503,450 shares of common stock at $6.00 per share which was equal to the purchase price at which shares were sold to the public in our initial public offering. The Notes were subordinate to the Company's term loan with Oxford Finance LLC.

January 2015 Private Placement

In January 2015, we completed a private placement of approximately 3.4 million shares of common stock at $5.85 per share. Proceeds from our private placement, net of commissions and other offering costs, were $19.3 million.

February 2015 Loan and Security Agreement

In February 2015, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., or Hercules for a term loan of up to $25.0 million. A first tranche of $16.5 million was funded upon execution of the loan agreement, approximately $15.5 million of which was used to repay our existing term loan with Oxford. We are scheduled to make interest-only payments on the loan until July 1, 2016, which period may be extended under certain circumstances. Under the terms of the loan agreement, we may, but are not obligated to, draw an additional tranche

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of up to $8.5 million prior to July 1, 2016, subject to the achievement of certain clinical milestones, which may be extended to December 31, 2016 under certain circumstances.

In connection with the loan agreement, we issued Hercules a warrant to purchase 180,274 shares of our common stock at an exercise price of $5.89 per share and granted Hercules the right participate in future equity financings in an amount up to $2.0 million while the loan and warrant are outstanding.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-10, which eliminates the concept of a development stage entity, or DSE, in its entirety from GAAP. Under current guidance, DSEs are required to report incremental information, including inception-to-date financial information, in their financial statements. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenue generated from that business. Entities classified as DSEs will no longer be subject to these incremental reporting requirements after adopting ASU No. 2014-10. ASU No. 2014 is effective for fiscal years beginning after December 15, 2014, with early adoption permitted. Retrospective application is required for the elimination of incremental DSE disclosures. Prior to the issuance of ASU No. 2014-10, we had met the definition of a DSE since our inception. We elected to adopt this ASU early, and therefore it has eliminated the incremental disclosures previously required of DSEs, beginning with our Quarterly Report on Form 10-Q for the period ended June 30, 2014.

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, financing, exchange rates or other factors. These market risks are principally limited to interest rate fluctuations.

We had cash and cash equivalents of $40.2 million at December 31, 2014 consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

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Item 8. Financial Statements and Supplementary Data

Agile Therapeutics, Inc.
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Report of Independent Registered Accounting Firm

The Board of Directors and Stockholders
Agile Therapeutics, Inc.

We have audited the accompanying balance sheets of Agile Therapeutics, Inc. as of December 31, 2014 and 2013, and the related statements of operations, convertible preferred stock and changes in stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Agile Therapeutics, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Metro Park, New Jersey
March 26, 2015

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Agile Therapeutics, Inc.

Balance Sheets

	December 31	
	2014	**2013**
Assets		
Current assets:		
Cash and cash equivalents	$ 40,182,141	$ 2,119,646
Prepaid expenses	803,775	146,704
Total current assets	40,985,916	2,266,350
Property and equipment, net	12,046,267	11,963,079
Prepaid expenses, long-term	1,677,434	
Deferred financing costs, net	98,401	157,499
Other assets	18,208	18,208
Total assets	$ 54,826,226	$ 14,405,136
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,631,217	$ 715,454
Accrued expenses	1,062,113	379,164
Loan payable, current portion	5,003,143	5,105,407
Warrant liability	296,048	644,478
Total current liabilities	8,992,521	6,844,503
Loan payable, long-term	9,827,758	9,769,528
Commitments and contingencies *(Note 13)*		
Series A-1, 8%, non-cumulative convertible preferred stock, $.0001 par value, authorized 284,743 shares; 0 shares issued and outstanding as of December 31, 2014 and 137,787 shares issued and outstanding as of December 31, 2013		898,305
Series A-2 convertible preferred stock, $.0001 par value, authorized 99,178 shares; 0 shares issued and outstanding as of December 31, 2014 and 66,116 shares issued and outstanding as of December 31, 2013		543,623
Series B, 8% non-cumulative, convertible preferred stock, $.0001 par value, authorized 4,510,066 shares; 0 shares issued and outstanding as of December 31, 2014 and 4,510,066 shares issued and outstanding as of December 31, 2013		44,928,382
Series C, 12% non-cumulative, convertible preferred stock, $.0001 par value, authorized 2,711,734 shares; 0 shares issued and outstanding as of December 31, 2014 and 1,578,400 shares issued and outstanding as of December 31, 2013		22,862,367
Stockholders' equity (deficit):		
Common stock, $.0001 par value, authorized 150,000,000 shares; 18,634,872 shares issued and outstanding as of December 31, 2014 and 109,321 shares issued and 103,536 shares outstanding as of December 31, 2013;	1,864	10
Additional paid-in capital	170,395,934	46,872,801
Accumulated deficit	(134,391,851)	(118,314,383)
Total stockholders' equity (deficit)	36,005,947	(71,441,572)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 54,826,226	$ 14,405,136

See accompanying notes.

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Agile Therapeutics, Inc.

Statements of Operations

	Year Ended December 31		
	2014	**2013**	**2012**
Operating expenses:			
Research and development	$ 13,364,704	$ 9,154,484	$ 17,386,961
General and administrative	5,150,512	3,573,893	5,929,890
Total operating expenses	18,515,216	12,728,377	23,316,851
Loss from operations	(18,515,216)	(12,728,377)	(23,316,851)
Other income (expense)			
Interest expense	(1,565,730)	(1,512,911)	(140,051)
Interest income	2,563	1,658	25,762
Change in fair value of warrants	348,430	(80,990)	171,013
Loss before benefit from income taxes	(19,729,953)	(14,320,620)	(23,260,127)
Benefit from income taxes	3,652,485		
Net loss	(16,077,468)	(14,320,620)	(23,260,127)
Beneficial conversion charge			(600,000)
Net loss attributable to common stockholders	$ (16,077,468)	$ (14,320,620)	$ (23,860,127)
Net loss per share (basic and diluted)	$ (1.41)	$ (289.39)	$ (603.78)
Weighted-average shares outstanding (basic and diluted)	11,394,971	49,486	39,518

See accompanying notes.

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Agile Therapeutics, Inc.

Statements of Convertible Preferred Stock and Changes in Stockholders' Equity (Deficit)

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Net Stockholde Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
ance ember 31, 2011	137,787	898,305	66,116	543,623	4,256,067	42,391,758			45,303	4	44,119,890	(80,133,636)	(36,013,7
ance of es B vertible ferred Stock, net ffering costs					253,999	2,536,624							
ance of es C vertible ferred Stock, net ffering costs							1,127,746	16,778,538					
version of missory notes accrued interest							450,654	6,083,829					
re-based pensation stock ons											665,454		665,4
med dividends											600,000	(600,000)	
loss for the ended ember 31, 2012												(23,260,127)	(23,260,1
ance ember 31, 2012	137,787	898,305	66,116	543,623	4,510,066	44,928,382	1,578,400	22,862,367	45,303	4	45,385,344	(103,993,763)	(58,608,4
re-based pensation stock ons											1,337,857		1,337,8
ance of mmon Stock for ployee bonuses									11,981	1	79,508		79,5
ance of mmon stock n exercise of ons									52,037	5	70,092		70,0
loss for the ended ember 31, 2013												(14,320,620)	(14,320,6
ance, ember 31, 2013	137,787	898,305	66,116	543,623	4,510,066	44,928,382	1,578,400	22,862,367	109,321	10	46,872,801	(118,314,383)	(71,441,5
re-based pensation stock ons											1,380,713		1,380,7
ance of mmon stock for ployee bonuses									9,983	1	79,999		80,0
version of ferred stock to mmon stock	(137,787)	(898,305)	(66,116)	(543,623)	(4,510,066)	(44,928,382)	(1,578,400)	(22,862,367)	8,803,547	882	69,231,796		69,232,6
version of es and accrued rest									503,450	50	3,020,617		3,020,6
									9,166,667	917	49,742,724		49,743,6

mmon stock ed in IPO, net xpenses					
rcise of stock ons	41,904	4	67,284		67,2
loss for the ended ember 31, 2014				(16,077,468)	(16,077,4
ance, ember 31, 2014	18,634,872	$ 1,864	$ 170,395,934	$ (134,391,851)	$ 36,005,9

See accompanying notes.

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Agile Therapeutics, Inc.

Statements of Cash Flows

	Year Ended December 31		
	2014	**2013**	**2012**
Cash flows from operating activities			
Net loss	$ (16,077,468)	$ (14,320,620)	$ (23,260,127)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	12,551	11,876	23,662
Noncash stock bonus	80,000	79,509	
Noncash stock based compensation	1,380,713	1,337,857	665,454
Noncash interest	185,731	132,911	83,829
Change in fair value of warrants	(348,430)	80,990	(171,013)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(2,334,504)	107,399	(33,792)
Accounts payable and accrued expenses	2,598,712	(448,748)	(275,958)
Net cash used in operating activities	(14,502,695)	(13,018,826)	(22,967,945)
Cash flows from investing activities			
Acquisition of property and equipment	(95,739)	(4,945,379)	(6,692,981)
Net cash used in investing activities	(95,739)	(4,945,379)	(6,692,981)
Cash flows from financing activities			
Proceeds from convertible bridge notes	3,000,000		6,000,000
Proceeds from issuance of term loan			15,000,000
Proceeds from issuance of preferred stock, net of offering costs			19,315,162
Proceeds from issuance of common stock in initial public offering, net of offering costs	49,743,641		
Cash paid for financing costs	(150,000)		(202,499)
Proceeds from exercise of stock options	67,288	70,097	
Net cash provided by financing activities	52,660,929	70,097	40,112,663
Net increase (decrease) in cash and cash equivalents	38,062,495	(17,894,108)	10,451,737
Cash and cash equivalents, beginning of year	2,119,646	20,013,754	9,562,017
Cash and cash equivalents, end of year	$ 40,182,141	$ 2,119,646	$ 20,013,754
Supplemental cash flow information			
Interest paid	$ 1,380,000	$ 1,380,000	$ 56,222
Income taxes paid	$	$	$
Supplemental disclosure of noncash financing activities			
Conversion of preferred stock into common stock	$ 69,232,677	$	$

Conversion of notes payable and interest into common stock	$	3,020,667	$	$

See accompanying notes.

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Agile Therapeutics, Inc.

Notes to Financial Statements

December 31, 2014

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. (the "Company") was incorporated in Delaware on December 22, 1997. The Company is engaged in research and development of transdermal patch technology for use in contraception. The Company's activities since inception have consisted principally of raising capital, and performing research and development. The Company is headquartered in Princeton, New Jersey.

The Company is devoting substantially all of its efforts toward research and development of its transdermal patch for use in contraception, and raising capital. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, the difficulties inherent in the development of commercially usable products, the potential need to obtain additional capital necessary to fund the development of its products, and competition from larger companies. The Company has incurred losses each year since inception. As of December 31, 2014, the Company had an accumulated deficit of approximately $134.4 million.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in its initial public offering (see Note 9), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding. The Company expects to continue to incur net losses into the foreseeable future.

As of December 31, 2014, the Company had cash and cash equivalents of $40.2 million. Although the Company has incurred recurring losses in each year since inception, the Company expects its cash and cash equivalents will be sufficient to fund operations for at least the next twelve months.

2. Summary of Significant Accounting Polices

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for preferred stock warrants, stock-based compensation, income taxes, and accounting for research and development costs. Actual results could differ from those estimates.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

2. Summary of Significant Accounting Polices (Continued)

Stock Split

On May 5, 2014, the Company effected a 1.4-for-1 stock split of the Company's common stock. All share and per share amounts of common stock contained in the Company's financial statements have been restated for all periods to give retroactive effect to the stock split. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' deficit reflects the stock split by reclassifying from "Additional paid-in Capital" to "Common Stock" in an amount equal to the par value of the increased shares resulting from the stock split.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. Cash and cash equivalents include money market funds that invest primarily in commercial paper and U.S. government and U.S. government agency obligations.

The Company, at times, maintains balances with financial institutions in excess of the FDIC limit.

Fair Value of Financial Instruments

In accordance with ASC 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash and cash equivalents are carried at fair value (see Note 3).

Financial instruments, including accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Property and Equipment

Property and equipment, consisting of manufacturing, office and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line, method over the estimated useful lives of the assets.

Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which costs are incurred. Improvements and additions are capitalized in accordance with Company policy.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe that there has been any impairment of the carrying value of any long-lived assets as of December 31, 2014.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expense consists primarily of costs related to personnel, including salaries and other personnel-related expenses,

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

2. Summary of Significant Accounting Polices (Continued)

expenses related to manufacturing, clinical trial expenses, consulting fees and support services used in drug development. All research and development costs are charged to operations as incurred in accordance with ASC 730, *Research and Development*.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Deferred Financing Costs

Costs directly attributable to the Company's term loan (see Note 8) are deferred and capitalized. These costs represent legal fees and other costs related to the term loan and are being amortized over the term of the loan. Amortization of deferred financing costs charged to interest expense was $59,100, $45,000 and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents. All cash and cash equivalents are held in business checking and money market accounts in United States financial institutions the balances of which, at times, exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. The Company believes it is not exposed to significant credit risks on cash and cash equivalents. The Company has no financial instruments with off-balance sheet risk of accounting loss.

Warrants

The Company accounts for its warrants to purchase redeemable convertible stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*. ASC 480 requires that a financial instrument, other than outstanding share, that, at inception, is indexed to an obligation to repurchase the issuer's equity shares, regardless of the timing or the probability of the redemption feature, and may require the issuer to settle the obligation by transferring assets be classified as a liability. The Company measures the fair value of its warrant liability using an option pricing model with changes in fair value recognized in the statement of operations.

In connection with the completion of the Company's initial public offering in May 2014, the warrants to purchase shares of Series A-1 and Series A-2 preferred stock expired unexercised and the warrants to purchase shares of Series C preferred stock automatically converted into warrants to purchase shares of common stock. These common stock warrants with non-standard anti-dilution provisions (referred to as down round protection) are classified as liabilities and re-measured each reporting period. As of December 31, 2014, there were outstanding 62,505 warrants to purchase common stock at $6.00 per share. These warrants expire on December 14, 2019.

Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

2. Summary of Significant Accounting Polices (Continued)

between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of December 31, 2014 that qualifies for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing models. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

Awards for consultants are accounted for under ASC 505-50, *Equity Based Payments to Non-Employees*. Any compensation expense related to consultants is marked-to-market over the applicable vesting period as they vest.

Prior to May 22, 2014, the Company utilized various methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its stock. The methodologies included an option pricing method and a probability-weighted expected return methodology that determined an estimated value under an initial public offering (IPO) scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of clinical trials and the time to completing an IPO or sale of the Company. As with any valuation, significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company views its operations

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

2. Summary of Significant Accounting Polices (Continued)

and manages its business in one operating segment, which is the business of developing its transdermal patch for use in contraception.

Comprehensive Income

Effective January 1, 2012, an update to an accounting standard was issued that requires all non-owner changes in stockholders' equity to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This update was applied retrospectively. The Company adopted this pronouncement and elected to present a separate statement of comprehensive income. The Company did not incur any components of comprehensive income for the periods presented and therefore, did not include a statement of comprehensive income in the financial statements.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding plus the effect of dilutive potential common shares outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of diluted net loss per share calculation, convertible preferred stock, convertible preferred stock warrants, common stock warrants and stock options are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive (in common equivalent shares):

	Year Ended December 31,		
	2014	2013	2012
Convertible preferred stock		6,292,369	6,292,369
Convertible preferred stock warrants		205,020	205,020
Common stock warrants	62,505		
Common stock options	1,817,548	1,163,621	1,341,731
Total	1,880,053	7,661,010	7,839,120

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-10, which eliminates the concept of a development stage entity, or DSE, in its entirety from GAAP. Under current guidance, DSEs are required to report incremental information, including inception-to-date financial information, in their financial statements. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

2. Summary of Significant Accounting Polices (Continued)

commenced or have commenced but there has been no significant revenue generated from that business. Entities classified as DSEs will no longer be subject to these incremental reporting requirements after adopting ASU No. 2014-10. ASU No. 2014 is effective for fiscal years beginning after December 15, 2014, with early adoption permitted. Retrospective application is required for the elimination of incremental DSE disclosures. Prior to the issuance of ASU No. 2014-10, the Company had met the definition of a DSE since its inception. The Company elected to adopt this ASU early, and therefore it has eliminated the incremental disclosures previously required of DSEs, beginning with its Quarterly Report on Form 10-Q for the period ended June 30, 2014.

3. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 Quotes prices in active markets for identical assets and liabilities. The Company's Level 1 assets and liabilities consist of cash and cash equivalents.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company has no Level 2 assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market data and which require internal development of assumptions about how market participant price the fair value of the assets or liabilities. The Company's Level 3 liabilities consist of the warrant liability.

The Company is required to mark the value of its warrant liability to market and recognize the change in valuation in its statements of operations each reporting period.

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of December 31, 2014 and 2013.

	Level 1	Level 2	Level 3
2014			
Assets:			
Cash equivalents	$ 40,135,102	$	$
Total assets at fair value	$ 40,135,102	$	$

Liabilities:			
Common stock warrants			296,048
Total liabilities at fair value	$	$	$ 296,048

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

3. Fair Value Measurements (Continued)

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2014 include (i) volatility (104.8%), (ii) risk free interest rate of 1.68% (estimated using treasury bonds with a 5 year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($6.14) and (v) expected life (five years)

The following is a rollforward of the fair value of Level 3 warrants:

Beginning balance at December 31, 2011	$	521,525
Issuance of Series C warrants		212,976
Change in fair value		(171,013)
Ending balance at December 31, 2012		563,488
Change in fair value		80,990
Ending balance at December 31, 2013		644,478
Expiration of Series A-1 and Series A-2 warrants		(493,361)
Change in fair value		144,931
Ending balance at December 31, 2014	$	296,048

	Level 1	Level 2	Level 3
2013			
Assets:			
Cash equivalents	$ 2,066,156	$	$
Total assets at fair value	$ 2,056,156	$	$
Liabilities:			
Series A-1 warrants	$	$	$ 438,978
Series A-2 warrants			64,537
Series C warrants			140,963
Total liabilities at fair value	$	$	$ 644,478

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2013 include (i) volatility (104.8%), (ii) risk free interest rate of 1.94% (estimated using treasury bonds with a 6 year life), (iii) strike price ($10.00) for the Series A-1 and Series A-2 warrants and $15.00 for the Series C warrants, (iv) fair value of Series A-1 preferred stock ($4.17), Series A-2 preferred stock ($2.91) and Series C preferred stock ($7.63) and (v) expected life (six years).

There were no transfers between Level 1, 2 or 3 during 2014 or 2013. If the Company's estimates regarding the fair value of its warrants are inaccurate, a future adjustment to these estimated fair values may be required. Additionally, these estimated fair values could change significantly.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

4. Prepaid Expenses

Prepaid expenses consist of the following:

	December 31	
	2014	2013
Prepaid clinical trial expense	$ 1,677,434	$
Prepaid insurance	761,842	48,055
Other	41,933	98,649
Total prepaid expenses	$ 2,481,209	$ 146,704
Prepaid expenses, short-term	$ 803,775	$ 146,704
Prepaid expenses, long-term	1,677,434	
Total prepaid expenses	$ 2,481,209	$ 146,704

Prepaid expenses, long-term represents non-refundable advances to the Company's clinical research organization which will be applied against final invoices in accordance with the contractual terms of the arrangement.

5. Property and Equipment

Property and equipment, consisting of manufacturing, office and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line, method over the estimated useful lives of the assets. Property and equipment consist of the following:

	December 31		Estimated
	2014	2013	Life
Office equipment	$ 54,468	$ 51,723	3 - 10 years
Computer equipment	95,145	65,746	3 years
Manufacturing equipment	12,182,297	12,118,702	5 years
	12,331,910	12,236,171	
Less: accumulated depreciation	(285,643)	(273,092)	
Property and equipment, net	$ 12,046,267	$ 11,963,079	

As December 31, 2014 and 2013, manufacturing equipment includes approximately $12.0 million and $11.9 million, respectively, of equipment which is in the process of being constructed and qualified and is not currently being depreciated.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

6. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31	
	2014	2013
Employee bonuses	$ 665,050	$ 238,941
Accrued clinical trial costs	254,333	
Other	142,730	140,223
Total accrued liabilities	$ 1,062,113	$ 379,164

7. Convertible Note Financing

On April 28, 2014, the Company and certain of the Company's existing preferred stockholders, all of whom qualify as accredited institutional investors, entered into a Convertible Subordinated Note Purchase Agreement pursuant to which such holders agreed to loan the Company an aggregate of $3.0 million. The Company issued Convertible Promissory Notes (the "Notes") to evidence its payment obligations with respect to the $3.0 million. The Notes had an interest rate of 8%, accruing daily and compounding annually. The Notes are convertible into unregistered equity securities of the Company upon the occurrence of events stated therein. The Notes and accrued interest automatically converted into 503,450 shares of common stock at $6.00 per share which was equal to the purchase price at which shares were sold to the public in an underwritten public offering (see Note 9). The Notes were subordinate to the Company's term loan with Oxford Finance LLC.

8. Term Loan

In December 2012, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford Finance") pursuant to which the Company borrowed a total of $15.0 million (the "Term Loan") from Oxford. The Term Loan accrues interest at a fixed annual interest rate equal to 9.20% (Three-month U.S. Libor rate of 0.47% plus 8.73%).

In January 2014, the Company amended its Loan Agreement with Oxford Finance whereby the interest only period was extended for an additional twelve months (through January 1, 2015) as a result of the Company's convertible note financing (see Note 7) and completion of the Company's initial public offering (see Note 9). In connection with the amendment to the Loan Agreement the Company has paid Oxford Finance a total of $150,000. The $150,000 has been offset against the amount of the loan and is being amortized to interest expense.

Interest on the Term Loan is payable monthly and principal is due in 30 equal consecutive monthly installments beginning on February 1, 2015 and ending on July 1, 2017. In addition, the Company is required to make a final payment of $675,000 on the maturity date of the Term Loan (July 1, 2017).

The Company may prepay all, but not less than all, of the Term Loan subject to a prepayment premium of 2% of the outstanding principal during the first twenty-four months of the Term Loan. From months twenty-five to loan maturity the prepayment premium is 0.75% of the outstanding principal. The obligations of the Company under the Loan Agreement are secured with a blanket lien on all assets of the Company, excluding its intellectual property assets. Under the Loan Agreement, the

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

8. Term Loan (Continued)

Company is subject to specified affirmative and negative covenants. The Loan Agreement provides, that, upon the occurrence of certain events of default, the Company's obligations under the Loan Agreement may be automatically accelerated, whereupon the Company's obligations under the Loan Agreement shall be immediately due and payable. At December 31, 2014, the Company believes it is in compliance with the Loan Agreement.

In connection with the Loan Agreement, the Company issued Oxford Finance warrants to purchase 25,002 shares of Series C Preferred Stock at $15.00 per share. The value of these warrants was calculated to be approximately $213,000 which is being accreted to interest expense ratably over the term of the loan. In connection with its initial public offering (see Note 9), the Series C preferred stock warrants were converted into 62,505 warrants to purchase common stock at $6.00 per share. These warrants expire on December 14, 2019.

Interest expense on the Term Loan including the accretion of the value of the related warrants and amortization of the deferred financing costs was approximately $1,545,100, $1,472,300 and $0 for the years ended December 31, 2014, 2013 and 2012, respectfully.

The annual maturities of the Term Loan, as of December 31, 2014, are as follows:

2015	$	5,105,407
2016		6,081,174
2017		3,813,419
Total	$	15,000,000

In February 2015, the Company terminated the Loan Agreement with Oxford (see Note 14)

9. Stockholders' Equity

Initial Public Offering and Related Transactions

On May 29, 2014, the Company completed its initial public offering selling 9,166,667 shares of common stock at $6.00 per share. Proceeds from the Company's initial public offering, net of underwriting discounts and commissions and other offering costs, were $49.7 million.

In addition, each of the following occurred in connection with the completion of the Company's IPO on May 29, 2014:

- the conversion of all outstanding shares of convertible preferred stock into 8,809,325 shares of the Company's common stock; and

- the conversion of the aggregate principal amount of $3.0 million and accrued interest under the Company's outstanding convertible subordinated promissory notes into 503,450 shares of the Company's common stock.

On May 7, 2014, the Company filed an amendment to its amended and restated certificate of incorporation which, among other things, revised the automatic conversion provision relating to the Series C Preferred Stock, Series B Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock. Following such amendment, the Series C, the Series B, the Series A-1 and A-2

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

9. Stockholders' Equity (Continued)

Preferred Stock automatically converted into shares of common stock at the then effective conversion price upon:

(i) the closing of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, covering the offer and sale of common stock from which the Company receives gross proceeds of at least $45,000,000 or (ii) the affirmative vote of the holders of at least a majority of the voting power the Series C Preferred Stock, the Series B Preferred Stock and the Series A-1 Preferred Stock, respectively, after first giving effect, if in conjunction with a public offering which does not meet the standards set forth in clause (i) above, to any adjustment of the conversion price for each series of preferred stock to which it would otherwise be entitled by virtue of such public offering.

On May 29, 2014, the Company filed an amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware in connection with the closing of the Company's initial public offering of shares of its common stock. The Company's board of directors (the "Board") and stockholders previously approved the Restated Certificate effective as of and contingent upon the closing of the Company's initial public offering.

The Restated Certificate amends and restates in its entirety the Company's second amended and restated certificate of incorporation, as amended. The Restated Certificate, among other things: (i) authorizes 150,000,000 shares of common stock; (ii) eliminates all references to the previously existing series of preferred stock; (iii) authorizes 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Board in one or more series; (iv) provides that the Board be divided into three classes with staggered three-year terms, with one class of directors to be elected at each annual meeting of the Company's stockholders; (v) provides that directors may only be removed with cause and only upon the affirmative vote of holders of at least 75% of the voting power of all then-outstanding shares of capital stock of the Company entitled to vote generally in the election of directors; (vi) provides that only the Board, the chairman of the Board, if one is appointed, or the chief executive officer may call a special meeting of stockholders; and (vii) requires that any action instituted against the Company's officers or directors in connection with their service to the Company be brought in the State of Delaware.

Convertible Preferred Stock (Prior to IPO)

Prior to its conversion in the IPO, the Company's convertible preferred stock was classified as temporary equity on its balance sheets instead of stockholders' (deficit) in accordance with authoritative guidance for the classification and measurement or redeemable securities. Upon certain change in control events that were outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock could cause its redemption.

Sales of Convertible Preferred Stock

In March 2012, the Company completed its Series B Preferred Stock financing by issuing the remaining 253,999 shares of Series B convertible preferred stock at a price of $10.00 per share resulting in net proceeds of approximately $2.5 million.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

9. Stockholders' Equity (Continued)

In July 2012, the Company entered into a Series C Preferred Stock Purchase Agreement (the "Series C Agreement") to issue a total of 2,711,734 shares of Series C Preferred Stock at a purchase price per share of $15.00. In July 2012, the Company issued the initial tranche of 1,578,400 shares of Series C Convertible Preferred Stock and received net proceeds of approximately $22.9 million.

The Company evaluated each series of its preferred stock and determined that each individual series is considered an equity host under ASC 815, *Derivatives and Hedging*. In making this determination, the Company's analysis followed the whole instrument approach which compares an individual feature against the entire preferred stock instrument which includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of each series of preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including (i) whether the preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of preferred stock were entitled to dividends, (iv) the voting rights of the preferred stock and (v) the existence and nature of any conversion rights. As a result of the Company's conclusion that the preferred stock represents an equity host, the conversion feature of all series of preferred stock is considered to be clearly and closely related to the associated preferred stock host instrument. Accordingly, the conversion feature of all series of preferred stock is not considered an embedded derivative that requires bifurcation.

The Company accounts for potentially beneficial conversion features under ASC 470-20, *Debt with Conversion and Other Options*. At the time of each of the issuances of convertible preferred stock, the Company's common stock into which each series of the Company's preferred stock is convertible had an estimated fair value less than the effective conversion prices of the convertible preferred stock. Therefore, there was no intrinsic value on the respective commitment dates for the convertible preferred stock instruments.

10. Equity Incentive Plans

The Company had granted stock options under an amended and restated 1997 Equity Incentive Plan (the "1997 Plan") and a 2008 Equity Incentive Plan (the "2008 Plan"). The plans provided for the granting of incentive and nonstatutory options and stock awards to consultants, directors, officers and employees. Such options are exercisable for a period of ten years and generally vest over a four-year period. In conjunction with the adoption of the 2008 Plan in April 2008, no additional grants were made from the 1997 Plan and issued options from the 1997 Plan remain outstanding. In 2014, the Company's Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan"). The 2014 Plan is the successor to the Company's 2008 Plan and 1997 Plan. In conjunction with the adoption of the 2014 Plan in 2014, no additional grants were made from the 2008 Plan and options from the 1997 Plan and the 2008 Plan remain outstanding. As of December 31, 2014, there were 395,598 shares available for future grant under the 2014 Plan.

Through December 31, 2014, the Company granted options to certain employees and nonemployees to purchase shares of common stock at exercise prices ranging from $0.71 to $1,928.57 per share. The Company recorded non cash stock based compensation expense of $1,380,713, $1,337,857 and $665,454 for the years ended December 31, 2014, 2013 and 2012, respectively, based on

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

10. Equity Incentive Plans (Continued)

the fair market value of the options granted at the grant date as determined using a Black-Scholes option pricing model. Stock-based compensation expense was as follows:

	Year Ended December 31,		
	2014	2013	2012
Employee	$ 1,184,864	$ 475,897	$ 509,747
Non-employee	195,849	861,960	155,707
Total	$ 1,380,713	$ 1,337,857	$ 665,454

Stock-based compensation expense related to stock options was allocated as follows:

	Year Ended December 31,		
	2014	2013	2012
Research and development	$ 617,061	$ 861,908	$ 343,990
General and administrative	763,652	475,949	311,464
Total stock-based compensation expense	$ 1,380,713	$ 1,337,857	$ 665,454

The following assumptions were used to compute employee stock-based compensation under the Black-Scholes option pricing model:

	2014	2013	2012
Risk-free interest rate	1.84%	1.73%	0.80%
Expected volatility	104.8%	104.8%	105.2%
Expected dividend yield	0%	0%	0%
Expected life (in years)	6.25	6.25	6.25

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on comparable companies in the biotechnology and pharmaceutical industries.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historic exercise behavior, management determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period.

Forfeitures. The Company reduces stock-based compensation expense for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

10. Equity Incentive Plans (Continued)

As of December 31, 2014, the unrecorded deferred stock-based compensation balance related to stock options was approximately $5.3 million and will be recognized over an estimated weighted-average amortization period of 1.98 years. The weighted average grant date fair value of options granted during the year ended December 31, 2014 was $7.00.

The following table summarizes the options outstanding, options vested and the options exercisable as of December 31, 2014 and 2013:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2012	649,275	$ 2.47	8.8 years	
Options granted	692,456	4.38		
Options cancelled/forfeited				
Options outstanding at December 31, 2012	1,341,731	$ 3.41	8.9 years	
Options granted	27,534	4.38		
Options exercised	(52,037)	1.35		
Options cancelled/forfeited	(153,607)	4.10		
Options outstanding at December 31, 2013	1,163,621	3.44	7.9 years	
Options granted	712,570	8.76		
Options exercised	(41,904)	1.61		
Options cancelled/forfeited	(16,739)	4.65		
Options outstanding at December 31, 2014	1,817,548	5.56	7.9 years	$ 3,363,242
Options exercisable at December 31, 2014	923,301	3.34	6.8 years	$ 2,999,337
Vested and expected to vest at December 31, 2014	1,817,548	5.56	7.9 years	

Intrinsic value in the above table was calculated as the difference between the Company's estimated stock price at December 31, 2014, of $6.14, and the exercise price, multiplied by the number of options. Intrinsic value for options exercised during 2014 amounts to $208,979.

11. Income Taxes

As of December 31, 2014, the Company had available net operating loss carryforwards ("NOL") of approximately $123.3 million and $82.1 million for federal and state income tax reporting purposes, respectively, which are available to offset future federal and state taxable income, if any, through 2034. The Company also has research and development tax credit carryforwards of approximately $2.9 million and $1.1 million for federal and state income tax reporting purposes, respectively, which are available to reduce federal income taxes, if any, through 2034 and state income taxes, if any, through 2029.

The Internal Revenue Code of 1986, as amended (the "Code") provides for a limitation on the annual use of NOL and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes, as defined by the Code that could significantly limit the Company's ability to utilize these carryforwards. At this time, the Company has not completed

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

11. Income Taxes (Continued)

a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation, due to the costs and complexities associated with such a study. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal and state income tax purposes.

The Company does not have any significant unrecognized tax benefits.

As of December 31, 2014, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2011 through December 31, 2013 are still subject to examination by major tax jurisdictions.

For all years through December 31, 2014, the Company generated research credit but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment in known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are presented below:

	December 31	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$ 46,853,000	$ 41,800,000
Research credit carryforward	3,683,000	3,110,000
Stock options and other	795,000	481,000
Total gross deferred tax assets	51,331,000	45,391,000
Valuation allowance for deferred tax assets	(51,331,000)	(45,391,000)
Net deferred tax assets	$	$

The gross deferred tax assets and the valuation allowance shown above represent the items which reduce the income tax benefit which would result from applying the federal statutory tax rate to the pretax loss and cause no income tax expense or benefit to be recorded for the years ended December 31, 2014 and 2013.

The net change in the valuation allowance for the years ended December 31, 2014 and 2013 was an increase of $4.7 million and $6.0 million, respectively, related primarily to net operating losses incurred by the Company which are not currently deductible.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

11. Income Taxes (Continued)

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,		
	2014	**2013**	**2012**
Federal income tax at statutory rate	34%	34%	34%
State income tax benefit, net of federal benefit	6.0%	5.7%	5.8%
Research and development tax credits	3.0%	2.7%	0.4%
Other	%	(1.4)%	(0.5)%
Increase to valuation allowance	(24.0)%	(41.0)%	(39.7)%
Effective income tax rate	19.00%	0.00%	0.00%

Sale of New Jersey Net Operating Losses

The Company received approval to sell a portion of the Company's New Jersey net operating losses (NOLs) as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other companies. On February 27, 2014, the Company completed the sale of NOLs totaling approximately $39.1 million and research and development credits totaling approximately $0.4 million for net proceeds of approximately $3.6 million. Such proceeds are reflected as a tax benefit for year ended December 31, 2014.

12. Related Party Transactions

Effective March 17, 2014, one of the Managing Partners of SmartPharma LLC, or SmartPharma, an entity which provides commercial and business development consulting services to the Company, was appointed Chief Commercial Officer. In connection with the appointment of this individual as Chief Commercial Officer, the Company amended its consulting agreement with SmartPharma to remove this individual from the list of persons providing service under the consulting agreement. SmartPharma invoiced the Company $126,500 of fees for the year ended December 31, 2014.

13. Commitments and Contingencies

Operating Leases

The Company leases approximately 7,000 square feet of office space in Princeton, NJ. The current term of the lease is for a two year period ending on November 30, 2015. The Company has an option to renew the lease for a term of three years.

Rent expense was $159,042, $141,854 and $113,962 for the years ended December 31, 2014, 2013 and 2012, respectively.

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

13. Commitments and Contingencies (Continued)

Future minimum annual lease commitments under the noncancelable operating lease in effect as of December 31, 2014 are as follows:

2015	$	148,729

14. Subsequent Events

The following events occurred subsequent to December 31, 2014 through the date the financial statements was available to be issued.

Private Placement

In January 2015, the Company completed a private placement of approximately 3.4 million shares of common stock at $5.85 per share. Proceeds from the Company's private placement, net of commissions and other offering costs were $19.3 million.

Loan and Security Agreement

In February 2015, the Company entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. ("Hercules") for a term loan of up to $25.0 million. A first tranche of $16.5 million was funded upon execution of the loan agreement, approximately $15.5 million of which was used to repay the Company's existing term loan with Oxford (see Note 8). The Company is scheduled to make interest only payments on the loan until July 1, 2016, which period may be extended under certain circumstances. Under the terms of the loan agreement, the Company may, but is not obligated to, draw an additional tranche of up to $8.5 million prior to July 1, 2016, subject to the achievement of certain clinical milestones, which may be extended to December 31, 2016 under certain circumstances.

In connection with the loan agreement, the Company issued Hercules a warrant to purchase 180,274 shares of the Company's common stock at an exercise price of $5.89 per share and granted Hercules the right participate in future equity financings in an amount up to $2.0 million while the loan and warrant are outstanding.

15. Quarterly Data (Unaudited)

The following tables summarize the quarterly results of operations for each of the quarters in 2014 and 2013. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited financial information and include all adjustments (consisting

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Agile Therapeutics, Inc.

Notes to Financial Statements (Continued)

December 31, 2014

15. Quarterly Data (Unaudited) (Continued)

only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein.

	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Total revenue	$	$	$	$
Operating expenses	$ 2,447,626	$ 3,494,710	$ 6,048,884	$ 6,523,996
Net income (loss)	$ 839,293	$ (3,718,401)	$ (6,353,362)	$ (6,844,998)
Basic net income (loss) per common share	$ 0.10	$ (0.46)	$ (0.34)	$ (0.37)
Diluted net income (loss) per common share	$ 0.01	$ (0.46)	$ (0.34)	$ (0.37)

	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Total revenue	$	$	$	$
Operating expenses	$ 4,228,361	$ 3,249,070	$ 3,321,389	$ 1,929,557
Net income (loss)	$ (4,605,416)	$ (3,619,879)	$ (3,690,955)	$ (2,404,370)
Basic net income (loss) per common share	$ (109.18)	$ (70.29)	$ (71.67)	$ (45.68)
Diluted net income (loss) per common share	$ (109.18)	$ (70.29)	$ (71.67)	$ (45.68)

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Management's Annual Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 11. Executive Compensation

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Item 14. Principal Accounting Fees and Services

The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as a part of this Annual Report on Form 10-K:

(a)

Financial Statements

The information concerning our financial statements, and Report of Independent Registered Public Accounting Firm required by this Item is incorporated by reference herein to the section of this Annual Report on Form 10-K in Item 8, entitled "Financial Statements and Supplementary Data."

(b)

Financial Statement Schedules

All schedules have been omitted because the required information is not present or not present in amounts sufficient to require submission of the schedules, or because the information required is included in the Financial Statements or notes thereto.

(c)

Exhibits

The list of exhibits filed with this report is set forth in the Exhibit Index following the signature pages and is incorporated herein by reference.

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Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 26, 2015.

AGILE THERAPEUTICS, INC.

By /s/ ALFRED ALTOMARI

Alfred Altomari
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ALFRED ALTOMARI Alfred Altomari	Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2015
/s/ SCOTT M. COIANTE Scott M. Coiante	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2015
/s/ KAREN HONG Karen Hong, Ph.D.	Director	March 26, 2015
/s/ JOHN HUBBARD John Hubbard, Ph.D.	Director	March 26, 2015
/s/ ABHIJEET LELE Abhijeet Lele	Director	March 26, 2015
/s/ WILLIAM T. MCKEE William T. McKee	Director	March 26, 2015
/s/ ANDREW SCHIFF Andrew Schiff, M.D.	Director	March 26, 2015
/s/ JAMES TURSI James Tursi, M.D.	Director	March 26, 2015

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Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (Incorporated by reference, Exhibit 3.1 to Company's Current Report on Form 8-K, file number 001-36464, filed May 30, 2014.)
3.2	Amended and Restated Bylaws of the Registrant. (Incorporated by reference, Exhibit 3.2 to Company's Current Report on Form 8-K, file number 001-36464, filed May 30, 2014.)
4.1	Specimen Certificate evidencing shares of Registrant's common stock. (Incorporated by reference, Exhibit 4.1 to Company's Third Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 9, 2014.)
4.2	Fifth Amended and Restated Registration Rights Agreement, dated as of July 18, 2012, by and among the Registrant and the parties listed therein, as modified by the Amendment to Registration Rights Agreement, dated as of May 5, 2014, by and among the Registrant and the parties listed therein. (Incorporated by reference, Exhibit 4.2 to Company's Third Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 9, 2014.)
4.3	Form of Warrant to Purchase Shares of Series C preferred stock, as modified by the First Amendment to Warrant to Purchase Stock, dated January 31, 2014. (Incorporated by reference, Exhibit 4.3 to Company's First Amendment of Registration Statement on Form S-1, file number 333-194621, filed on April 17, 2014.)
10.1+	Form of Indemnification Agreement. (Incorporated by reference, Exhibit 10.1 to Company's Second Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 5, 2014.)
10.2+	Agile Therapeutics, Inc. Amended and Restated 1997 Equity Incentive Plan, as amended, and form of Stock Option Agreement thereunder. (Incorporated by reference, Exhibit 10.2 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.3+	Agile Therapeutics, Inc. Amended and Restated 2008 Equity Incentive Plan and form of Nonqualified Stock Option Agreement and form of Incentive Stock Option Agreement thereunder. (Incorporated by reference, Exhibit 10.3 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.4+	Agile Therapeutics, Inc. 2014 Incentive Compensation Plan and form of Stock Option Agreement, form of Non-Employee Director Stock Option Agreement and form of Restricted Stock Unit Issuance Agreement thereunder. (Incorporated by reference, Exhibit 10.4 to Company's Third Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 9, 2014.)
10.5+	Employment Agreement, dated October 11, 2010, by and between the Registrant and Alfred Altomari, as modified by the Amendment No. 1 to the Employment Agreement, dated December 12, 2012, by and between the Registrant and Alfred Altomari. (Incorporated by reference, Exhibit 10.4 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.6+	Offer Letter, dated November 23, 2010, by and between the Registrant and Scott Coiante. (Incorporated by reference, Exhibit 10.5 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)

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Exhibit Number	Description
10.7+	Offer Letter, dated December 9, 2013, by and between the Registrant and Dr. Elizabeth Garner. (Incorporated by reference, Exhibit 10.6 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.8+	Offer Letter, dated March 12, 2014, by and between the Registrant and Katie MacFarlane. (Incorporated by reference, Exhibit 10.7 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.9*	Development, License and Commercialization Agreement, dated October 18, 2006, by and between the Registrant and Corium International, Inc. as modified by the Addendum to the Development, License and Commercialization Agreement, dated January 10, 2012, by and between the Registrant and Corium International, Inc. and Addendum No. 2 to Development, License and Commercialization Agreement, dated February 6, 2013, by and between the Registrant and Corium International, Inc. (Incorporated by reference, Exhibit 10.9 to Company's Second Amendment of Registration Statement on Form S-1, file number 333-194621, filed on May 5, 2014.)
10.10	Loan and Security Agreement, dated December 14, 2012, by and between the Registrant and Oxford Finance LLC, as modified by the First Amendment to the Loan and Security Agreement, dated January 31, 2014, by and between the Registrant and Oxford Finance LLC. (Incorporated by reference, Exhibit 10.9 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.11	Consulting Agreement, dated October 16, 2009, by and between the Registrant and SmartPharma LLC, as modified by the Amendment to Consulting Agreement, dated February 22, 2013, by and between the Registrant and SmartPharma LLC, and Amendment No. 2 to Consulting Agreement, dated March 1, 2014, by and between the Registrant and SmartPharma LLC. (Incorporated by reference, Exhibit 10.10 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
10.12	Lease Agreement, dated November 19, 2010, by and between the Registrant and Bunn Farm Associates, LLC, as modified by the Lease Amendment, dated November 20, 2012, by and between the Registrant and Bunn Farm Associates, LLC, and the Second Lease Amendment, dated July 24, 2013, by and between the Registrant and Bunn Farm Associates, LLC. (Incorporated by reference, Exhibit 10.11 to Company's Registration Statement on Form S-1, file number 333-194621, filed on March 17, 2014.)
23.1	Consent of Ernst & Young LLP.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 26, 2015.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 26, 2015.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 26, 2015.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 26, 2015.

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Exhibit Number	Description
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements.

+ Indicates management contract or compensatory plan or arrangement.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.