2019 Annual Report

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the year ended December 31, 2019

OR

☐ **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	Trading Symbol(s)	Name of exchange on which registered:
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital 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 ☐ No ☒

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 ☐ No ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 28, 2019 was approximately $52.1 million.

As of February 18, 2020, there were 69,810,305 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2019, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

Agile Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2019

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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," "designed," "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 Annual Report on 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 manufacturing and commercialization of Twirla®, the potential market uptake of Twirla® and the development of our potential 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 potential product candidates, the legal and regulatory landscape impacting our business, 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 Annual Report on 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 Annual Report on 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 Annual Report on 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:

- our ability to successfully launch and commercialize Twirla;
- our ability along with the ability of our third-party manufacturer, Corium International, Inc.'s, or Corium, to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- the rate and degree of market acceptance of Twirla and any of our product candidates;
- the size and growth of the markets for Twirla and our product candidates and our ability to serve those markets;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of Twirla and our potential product candidates or other materials required for a clinical trial or other tests and studies;
- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;
- the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer;
- our ability to design and successfully complete a post-marketing long-term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and conduct a small post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla;
- our ability to maintain regulatory approval of Twirla and our ability to obtain regulatory approval of our potential product candidates, and the labeling under any approval we obtain;
- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;
- the success and timing of our clinical trials or other studies, including post-marketing studies for Twirla;
- our plans to develop our other potential product candidates;
- the successful development of our sales and marketing capabilities, including our ability to recruit, train, and retain an effective sales force or failure to build-out and implement an effective health care compliance program;
- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Annual Report on 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 Annual Report on Form 10-K. You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on 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 Annual Report on 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 any of 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 Annual Report on 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.

Item 1. Business Overview

Overview

We are a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla® and our potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Twirla, our first and only approved product, is a once-weekly prescription combination hormonal contraceptive patch. Twirla is designed using our proprietary transdermal patch technology, called Skinfusion®, designed with properties to optimize patch adhesion and patient wearability, which may help support compliance while, for the first time in a contraceptive patch, delivering a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs. We believe there is an unmet market need for a contraceptive patch that is designed to deliver approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient dosage form that may support compliance in a non-invasive fashion.

Twirla was approved for sale in the United States on February 14, 2020 as a method of contraception for use in women of reproductive potential with a body mass index (BMI) < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the observed relationship between efficacy and BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs.

As part of Twirla's approval, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The FDA's requirement for Twirla is similar to another post-marketing study requirement for a recently approved CHC. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a small post-marketing commitment PMC study to assess the residual drug content and strength of Twirla. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance entitled Transdermal and Topical Delivery Systems—Product Development and Quality Considerations. We are evaluating the design and cost of these post-marketing studies. With the approval of Twirla we now plan to focus on our transition from a clinical development stage company to a commercial company. During 2020, we plan to begin the implementation of our commercialization plan for Twirla and to manage the growth of our company. Our near-term plan for the commercialization of Twirla includes:

Activity	Expected Timing
Initiate coverage and reimbursement activities in the United States from third-party payors	First Quarter 2020
Initiate hiring of contract sales force	Second Quarter 2020
Complete pre-validation and validation of the commercial manufacturing process consistent with our approved marketing application	Second Half 2020 with first shipment of product anticipated in the Fourth Quarter 2020

Our Strategy

Our short-term goal is to establish an initial franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. To that end, our goal is to begin the pre-validation and validation of the

commercial manufacturing process in the first half of 2020, manufacture three validation batches of Twirla and complete the validation process in the second half of 2020. At the same time, we will prepare for the availability of commercial product supply. In the first quarter of 2020, we plan to initiate work with managed care and patient payors to gain market access for Twirla. In the second quarter of 2020, we plan to begin hiring and training an initial sales team, which we estimate to be in the range of 70 to 100 persons. We intend to ship product to wholesalers in the fourth quarter of 2020. During 2020, we also expect to begin planning the buildout of our existing pipeline and explore other opportunities to add additional products to our business.

Our current priorities are as follows:

- Successfully complete the pre-validation and validation process for the commercial manufacturing of Twirla;
- Obtain coverage and reimbursement for Twirla in the United States from third-party payors;
- Implement our commercialization plans for Twirla to ensure a successful launch in the United States, including building a sales and marketing team and implementing a healthcare compliance program;
- Establish a supply chain for Twirla that will support commercialization across the United States at launch;
- Complete the design and protocol of the FDA-required post-marketing long-term observational study comparing risks for VTE and ATE in new users of Twirla to new users of other CHCs;
- Explore the advancement of our existing pipeline and its possible expansion through business development activities.

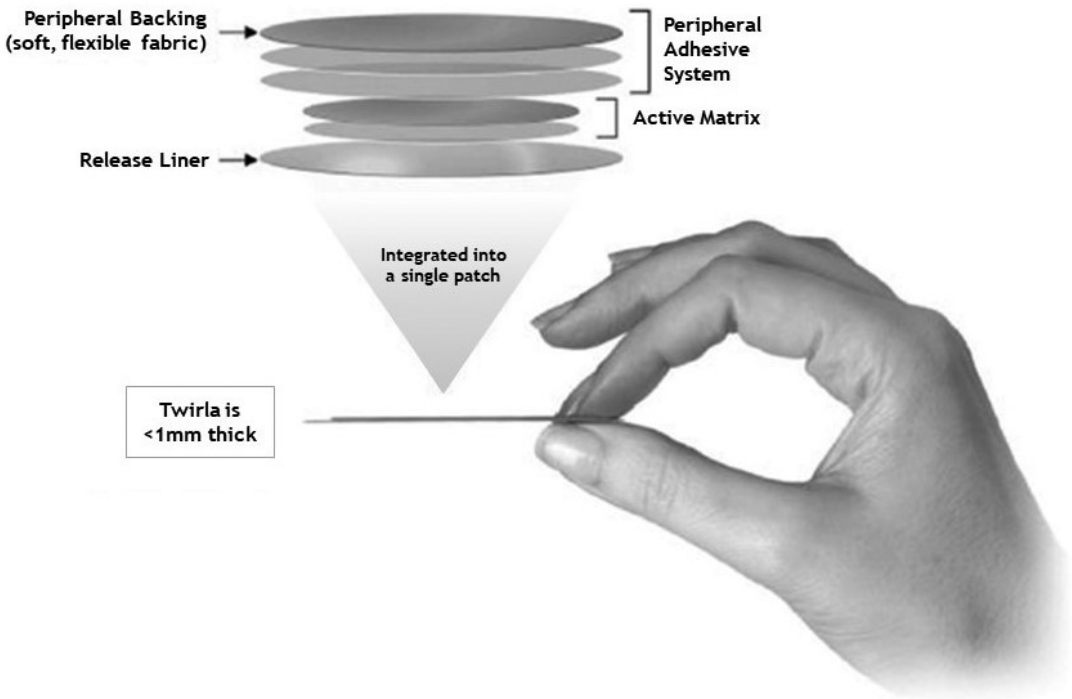
Twirla

Twirla is our first and only approved product, indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the reduced efficacy seen with increasing BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs.

Twirla is a prescription 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, both of which have an established history of efficacy and safety in currently marketed combination oral contraceptives. Twirla delivers approximately 30 micrograms of EE per day, a dose of EE consistent with the dose delivered by many commonly prescribed oral contraceptives. Our Skinfusion technology allows Twirla to be the first approved patch capable of delivering a contraceptive dose of LNG across the skin. The patch is applied once weekly for three weeks, followed by a week without a patch. Twirla is packaged with three individually wrapped patches per carton to provide for one 28-day cycle of therapy.

Twirla is designed for convenient application by patients as a method of contraception. By delivering active ingredients over seven days, in a comfortable, convenient and easy-to-use weekly patch, Twirla is designed around principals of ease of use, which may support enhanced patient compliance. It is also designed with properties to optimize patch adhesion and patient wearability with low levels of skin irritation. The patch is round and made of a soft, flexible 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

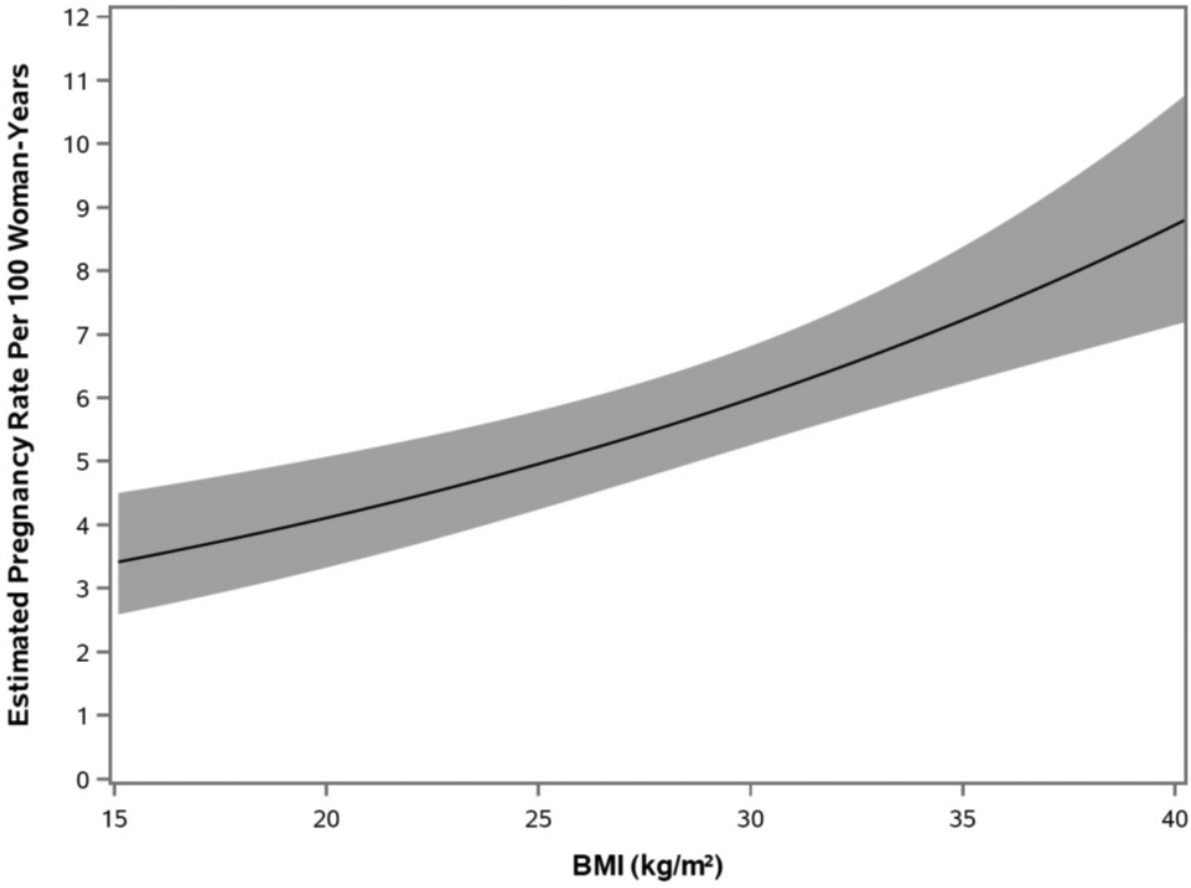
Lactate, Capric Acid and Lauryl Lactate, which are ingredients to assist in the transport of EE and LNG across the skin, and adhesives that enable adherence to the skin. The final top layer is the one seen when placed on the skin, and consists of a thin, cloth-like material consisting only of adhesive. 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 breaking down the adhesive there. 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 five layers of the patch are integrated to create a patch that has a slim profile and is unobtrusive when applied.



Twirla Marketing Authorization

Twirla received FDA approval on February14, 2020 as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the reduced efficacy seen with increasing BMI, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs.

Pregnancy Rates (Estimated*) in Twirla-Treated Patients as BMI Increases for Women ≤35 Years of Age in Study ATI-CL23



* The solid line displays the estimated pregnancy rate, and the shaded area displays the 95% confidence interval for the estimated pregnancy rate.

Twirla's approval is primarily based on safety and efficacy data from the Phase 3 SECURE trial. Because the Twirla NDA was submitted under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, and 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.

The SECURE trial was a multicenter, single-arm, open-label, 13-cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2,032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The trial was designed in consultation with the FDA, and incorporated a number of stringent trial design elements, including exclusion of treatment cycles not only for use of back-up contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on body mass index, or BMI, or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups. These entry criteria resulted in the inclusion of a substantial number of women with high BMI, who have frequently been under-represented in past contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent-to-treat population of subjects 35 years of age and under. The FDA also requested inclusion of pre-specified efficacy analyses related to BMI and body weight.

As part of Twirla's approval, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The FDA's requirement for Twirla is similar to another post-marketing study requirement for a recently approved CHC. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla in a minimum of 25 women. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance entitled *Transdermal and Topical Delivery Systems—Product Development and Quality Considerations.* We are evaluating the design and cost of these post-marketing studies.

Contraceptive Landscape and Market Opportunity

U.S. Hormonal Contraceptive Market Background

Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Examples of non-hormonal products available in the United States include the diaphragm, male condom, female condom, and non-hormonal intrauterine device, or IUD. Hormonal 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 several categories of hormonal contraception products available in the United States, including:

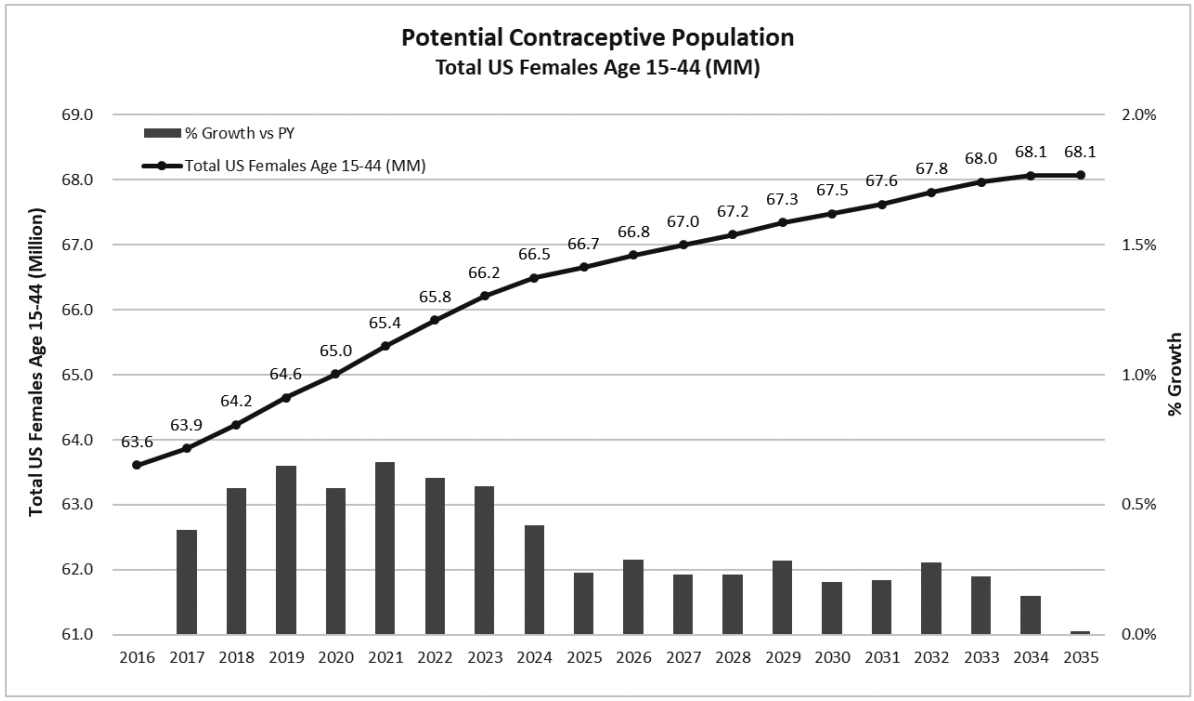
- oral contraceptive;
- vaginal ring;
- transdermal patch;
- hormonal IUD;
- subcutaneous implant; and
- injectable.

The U.S. hormonal contraceptive market is a multi-billion-dollar market. 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. The CHC portion of the market, which includes pills, two transdermal patches, including Twirla, and two vaginal rings, 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.

The U.S. hormonal contraceptive market is a mature market, with many branded and generic products available. Since the mid-2000s, CHC market growth as measured by prescription volume (TRx) has been flat to declining, with the exception of a 4.8% increase in 2013 compared to 2012. In the past three years (2017-2019), while CHC TRx growth has appeared to decline more aggressively (by 6%-12% per year), we believe this is largely due to an increase in the average TRx size (i.e. number of contraceptive cycles dispensed per TRx), which has increased from 1.4 cycles/TRx in 2016 to 1.7 cycles/TRx in 2019. The total cycles dispensed in 2018 and 2019 has remained relatively stable reflecting the continued flat growth of this mature market. While gross sales were relatively flat between 2014 and 2018 due to a lack of new product entries and increased generic competition for both the total hormonal contraceptive market and the CHC market, CHC market sales grew by 5.9% in 2019 vs. 2018 to a total of $4.1 billion, largely due to price increases.

We believe there are several possible factors primarily affecting prescription volume in the contraceptive market. 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 0.3% to 0.9% per year since 2011, increasing this population by approximately 200,000 to 580,000 women per year.



Source: U.S. Census Bureau, 2017 National Dataset (2016 is base population estimate for projections).

Additionally, 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 one-time phenomenon, as the market volume growth has been relatively flat since 2014, with the exception of a one-time drop in TRx cycles dispensed in 2017.

During the period following enactment of the ACA, generic oral contraceptive volume has shown the greatest growth, primarily at the expense of branded oral contraceptives. This is likely due to the policies that were implemented by many managed care plans, which generally only provided generic oral contraceptives with no cost-sharing to the patient. The effect on non-oral products is less clear, but volume for the vaginal ring showed a 6.8% decline from 2015 to 2019, while the prescription volume for the patch increased by 31% over the same time period. In May 2015, several government agencies, including the U.S. Department of Health and Human Services, or HHS, the Department of Labor, or DOL, and the U.S. Department of Treasury, or Treasury, jointly issued a clarification in the form of an FAQ which clarified the requirements for coverage of contraceptives under the ACA. The FAQ states

that plans and issuers must cover without cost-sharing at least one form of contraception in each of the 18 current methods that the FDA has identified for women in its current Birth Control Guide. The patch is identified as a specific method in the FDA Birth Control Guide, and therefore insurers must cover at least one patch product with no cost-sharing to the patient.

Despite the availability of generic contraceptives for over 25 years, branded products have maintained a significant, though declining, share of CHC sales. 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 2019, the average annual price increase among the top branded products was 10.5%. 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 $160.88 by December 2019. As of October 2014, the branded CHC transdermal patch (Ortho Evra) has been discontinued, and the generic CHC transdermal patch (Xulane) is currently priced at $122.15 per cycle. The other non-oral form of CHC, the vaginal ring, is currently priced at $162.63 per cycle. We cannot predict whether the manufacturers of branded products will continue to increase prices going forward. We have not yet set a WAC price for Twirla, but we believe we will be able to set one that is comparable to other branded and branded generic CHC products at the time of launch.

Contraceptive Pills

Based on 2014 data from the CDC, of women who choose to use a hormonal contraceptive, approximately 64% use a contraceptive pill, vaginal ring or patch, the majority of whom use the contraceptive pill. The remaining 36% of women using hormonal contraception are split between using injectables, implants, or IUDs. Based on this information, 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 an addition to the boxed warning that was 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 stabilized, with a 1.5% share of the market based on combined prescriptions for Evra and its generic equivalent (Xulane®) in

2014. In more recent years, the Xulane share of the CHC market TRx has grown, with a 1.8% share in 2017, 2.4% share in 2018, and 2.4% share in 2019.

In April 2014, Mylan Inc. announced the launch of Xulane®. In recent years, the Xulane share of the CHC market has grown slightly, with a 1.7% TRx share in 2016 and 1.8% TRx share in 2017. 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.

The FDA has maintained, in spite of the wording in the labeling for Evra, which has been discontinued, and its approved branded generic, that none of the epidemiologic studies provides a definitive answer regarding the relative risk of VTE with Evra compared to combined oral contraceptive use or whether the increased risk that some studies demonstrated is directly attributable to Evra. In spite of the labeling changes, and Johnson & Johnson ceasing promotion of Evra in 2007, Evra and its generic equivalent continue to generate significant sales.

With its approval on February 14, 2020, Twirla is now the only other transdermal contraceptive patch approved by the FDA. We believe that the rapid uptake and acceptance of Evra upon its introduction and its (and Xulane's) continued sales over the past several years demonstrate a market opportunity for multiple choices in transdermal contraceptive patches.

Twirla Potential Market Share

Three of our market research studies have included an allocation exercise to estimate the potential uptake of Twirla and peak market share. In all of these studies, ObGyns and nurse practioners, or NPs, indicated their allocation of contraceptive prescriptions before and after reviewing a product profile like Twirla that reflects the safety and efficacy results from our SECURE clinical trial. In the 2010 study, which was conducted prior to the implementation of the ACA, ObGyns estimated use of a product like Twirla in 17% of their CHC patients. A proprietary calibration model developed by the research firm 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. In the study completed in December 2016, ObGyns, NPs, and physicians assistants, or PAs, estimated use of Twirla in 22% of their CHC patients, which was also calibrated to adjust for overstatement, resulting in an estimated peak market share of 14% of the CHC market. This estimate was confirmed in our most recent study completed in September of 2019, in which ObGyns and NPs/PAs estimated use of Twirla in 20% of their CHC patients, calibrated to 14% of the CHC market.

We continue to evaluate the commercial opportunity for Twirla. We believe that the potential new CHC users who are within Twirla's approved indication represent a significant population of women. Based on the Company's market research, analysis of the current and expected future U.S. contraceptive market, and review of other product launches in the category, the Company estimates that Twirla can potentially achieve a peak market share of 5-8%. As we prepare for the commercialization of Twirla, we will continue to analyze the contraceptive market and update our market research for Twirla.

Twirla Commercialization Strategy

In January 2018, following our receipt of the complete response letter, or CRL, we received in December 2017, or 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, including commercial pre-launch and manufacturing validation activities. With the approval of Twirla, we have begun to accelerate our commercial activities. In the first quarter of 2020, we plan to

initiate work with managed care and patient payors to gain market access for Twirla. In the second quarter of 2020, we plan to begin hiring and training an initial sales team, which we estimate will consist of 70 to 100 persons. At the same time, we are currently preparing to initiate the validation of our commercial manufacturing process and expect to complete the validation process and commence distributing product to wholesalers in the fourth quarter of 2020. We will need to raise additional funds to complete these activities, and our ability to complete such activities according to our current planned timelines will depend on our ability to successfully raise the necessary capital.

Twirla Promotion Strategy

We have a limited number of sales and marketing employees. We plan to expand our commercial team, but will primarily rely on third-party agencies with experience in commercializing pharmaceutical products to advance the commercialization of Twirla. Our marketing efforts will initially focus on Obstetrician-gynecologists in the United States, and we plan to use a significant number of samples in the early stage of commercial launch to gain patient trial and acceptance. 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 ObGyn, NP and PA prescribers who are responsible for approximately 70% of branded CHC prescriptions. 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 use both branded and unbranded campaigns to create awareness of Twirla and available contraceptive options among consumers. We believe there are cost-effective means to reach our target demographic of females aged 18 to 34 years, who tend to engage in online activities to a high degree and 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. We believe that a focused consumer promotion plan that uses digital media, potential social media advertising, and other mass-market advertising vehicles will generate consumer awareness and demand for Twirla.

Twirla Coverage and Reimbursement Strategy

We initiated research with managed care and patient payors in the fourth quarter of 2019 to ensure we have a thorough understanding of the management of the contraceptive category. In the first quarter of 2020 we will continue to monitor competitive activity, assess the most probable formulary positions with identified target accounts and prepare for commercialization, including making limited company and portfolio presentations to payors within FDA guidelines. Also, in the first quarter of 2020, we will begin to meet with formulary decision makers as appropriate to rapidly secure positions for Twirla that minimize access barriers for prescribers and patients. We believe that it is important in this category for women to have equal access to all methods, dosing regimens and hormonal options so that they and their provider can select the choice that is the most appropriate to meet their lifestyle and family planning goals.

Topline Summary of Our Managed Care Market Research:

The managed care research summarized below was conducted with medical and pharmacy directors in the fourth quarter of 2019. In regard to forward-looking questions, subjects were asked to

assume that the ACA and Contraceptive Mandate would still be in effect. Our recent managed care research found the following:

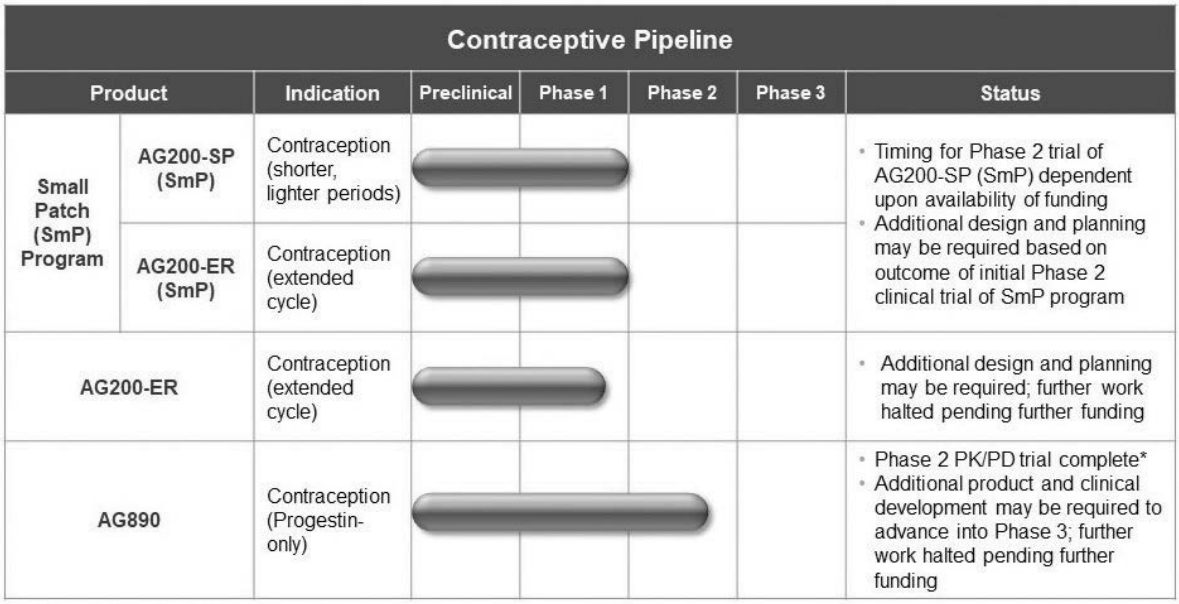
- Payors generally do not aggressively manage this category due to the ACA mandate for preventative care and have limited management controls in place;
- Management philosophy varies widely in this category from broad coverage at low copays to preferred/nonpreferred drugs mainly managed by tier placement;
- Most payors do not require a full review by their Pharmacy and Therapeutics Committee, so coverage is determined quickly, and brands may be covered at $0 copay if there is no corresponding generic available; and
- Several research participants noted that although there were many options in the category, there was a need for improvement around safety, tolerability, and improvement in patch adhesiveness.

Our Pipeline: Twirla Line Extensions and Potential Product Candidates

Twirla is our first and only approved product, and substantially all of our resources are committed to the manufacturing validation and commercialization of Twirla. We have halted all further work on our pipeline. We will require additional capital to conduct required post-market studies of Twirla and, should we choose, to advance the development of Twirla line extensions and our potential product candidates.

Our potential product pipeline consists of two classes of product candidates: Twirla line extensions and other transdermal contraceptive product candidates. These potential product candidates are designed to address market needs and offer additional non-daily contraceptive options. Based on the results of our market research online extension regimen concepts conducted in December 2016, we believe that our potential line extension product candidates may be commercially viable and could garner a share of the contraceptive market.

The current status of our potential product candidate pipeline is summarized in the graphic below:



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 and/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. In addition, the potential line extension product candidates in our pipeline will utilize a unique aspect in the regimen, where a smaller patch, or SmP, that delivers a lower dose of both EE and LNG will be worn during the final seven days of each cycle, rather than having a patch-free week, to allow for withdrawal bleeding while minimizing hormonal fluctuations and potentially the side effects that accompany changes in hormone levels. These regimens are protected by patents issued to us in 2015. A study to examine the pharmacokinetics and pharmacodynamics of the SmP will be required prior to advancing the potential line extension product candidates through clinical development.

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 and thus have fewer periods per year. 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. AG200-ER utilizes the same drug product as Twirla during the active phase of the cycle. We are currently evaluating the optimal cycle length to advance into Phase 3 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 comprise 46% 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 the same drug product as Twirla for the first three weeks of the cycle, and a smaller lower-dose patch, or SmP, in the fourth week, which will allow patients to continuously apply patches without interruption. AG200-SP requires additional patch development work on the SmP prior to potentially conducting a pharmacodynamics and pharmacokinetic study.
- AG200-ER (SmP) is an extended cycle regimen utilizing our current patch product and the SmP that is designed to allow a woman to extend the time between her episodes of withdrawal bleeding and experience shorter, lighter periods. By adjusting the length of the contraceptive cycle, AG200-ER (SmP) is designed to potentially minimize breakthrough bleeding and spotting, which are commonly reported concerns with patients using an extended regimen contraceptive product. AG200-ER (SmP) utilizes the same drug product as Twirla during the active phase of the cycle and will utilize the SmP during the final week of the cycle. AG200-ER (SmP) requires additional patch development work on the SmP prior to potentially conducting a pharmacodynamics and pharmacokinetic study.

Our other potential 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 ½ trial with AG890. The Phase ½ study was a multicenter study to evaluate the pharmacokinetics, safety, and mechanisms of potential contraceptive efficacy of AG890. The trial is complete, and we continue to evaluate the findings. Once we have completed our analysis of the data, it is possible that additional patch development work for dose selection may 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 potential product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we continue to review the clinical path and the budgetary requirements for each of these three potential product candidates.

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 non-hormonal barrier methods, such as the contraceptive sponge, diaphragm, cervical cap or shield and condoms. Then, there are hormonal methods, which is the category for Twirla and our potential product candidates, such as oral contraceptives, injections, implants, hormonal IUDs and vaginal ring and transdermal contraceptive products.

The following table is the FDA Birth Control Chart, which outlines the 18 unique forms of birth control and compares the effectiveness of each method.

U.S. FOOD & DRUG ADMINISTRATION
www.fda.gov/birthcontrol

BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

Most Effective

Least Effective

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects* This chart does not list all of the risks and side effects for each product
Sterilization Surgery for Women	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	Onetime procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection
IUD Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne Mood swings or depressed mood Headache
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ Bleeding between periods Headaches Nervousness Abdominal discomfort Weight gain Dizziness
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Pill" (Extended/ Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea Breast tenderness Skin irritation Stomach pain Headache
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache Nausea Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
OTHER CONTRACEPTION			
Emergency Contraceptives (EC): May be used if you did not use birth control or if your regular birth control fails (such as a condom breaks). It should not be used as a regular form of birth control. Emergency contraception prevents about 55 - 85% of predicted pregnancies.			
Levonorgestrel 1.5 mg (1 pill) Levonorgestrel .75 mg (2 pills)	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills as soon as possible within 3 days after having unprotected sex.	Menstrual changes Headache Dizziness Breast pain Lower stomach (abdominal) pain Nausea Vomiting Tiredness
Ulipristal Acetate	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills within 5 days after having unprotected sex.	Headache Abdominal pain Tiredness Nausea Menstrual pain Dizziness

*For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5):397-404

Although there are over 250 CHC products currently available, including brands and generics, just twelve branded products make up approximately half of total market sales. Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. The branded products with established market presence include, Nuvaring®, marketed by Merck, the only contraceptive vaginal ring available on the market, the Loestrin® franchise, marketed by Allergan (formerly known as Actavis), consisting of three oral contraceptives, Minastrin® 24, LoLoestrin® and Taytulla®, and Beyaz®, Yaz®, Yasmin® and Natazia® marketed by Bayer. Xulane, the branded generic to Ortho Evra and the only other patch currently available on the market, generated $297 million in sales for Mylan in 2019. Additionally, several generics manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz, Glenmark, Lupin, Amneal and Mylan. Based on the market experience of other non-oral CHC dosage forms, including Evra and Nuvaring, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

There are other hormonal contraceptive products, recently approved or in development that may compete with Twirla and our other potential product candidates. Annovera™, a vaginal ring developed by the Population Council, Inc. and licensed for commercialization by TherapeuticsMD, was approved on August 10, 2018 and began distribution August 15, 2019. Slynd®, a progestin-only pill containing drosperinone, was introduced by Exeltis in August of 2019. The Population Council also has a transdermal gel contraceptive in Phase 2, developed in collaboration with Antares Pharma, Inc. Two generics to Nuvaring were introduced in December 2019, EluRyng™ by Amneal and EVE-112 by Prasco Labs. Other companies that have new hormonal contraceptive products in various stages of development include Bayer, with a contraceptive patch and a P-only vaginal ring, both in Phase 3 development. Allergan has a P-only ring for which they received a CRL from the FDA. Mithra Pharmaceuticals SA announced Phase 3 data for a combination oral contraceptive in January 2019, and licensed this product to Mayne Pharma for distribution in the U.S. In the past few years, some of the large pharmaceutical companies such as Johnson & Johnson, Pfizer, and Teva 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, although they recently signed a license agreement with Dare Bioscience for U.S. commercial rights to Ovaprene, a hormone-free monthly contraceptive vaginal ring.

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 a new drug application, or NDA, filed for an oral contraceptive containing gestodene and EE in 1988, and Wyeth planned on 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 and rely on Corium for all aspects of the manufacturing of Twirla. We, along with Corium, 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. 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.

We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the equipment qualification and validation related to Corium's manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla. In September 2019, we re-started manufacturing development at Corium. We are currently working with Corium to complete manufacturing development and process improvements and plan to commence pre-validation work when that work is complete. Our goal is to manufacture three validation batches of Twirla and complete the pre-validation and validation of the commercial manufacturing process consistent with our approved marketing application in the second half of 2020.

In 2006, we entered into an exclusive agreement with Corium to develop Twirla using our Skinfusion technology, and also for AG890, which is a progestin-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 the 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. Corium needs to complete the validation of the commercial manufacturing process for Twirla and potentially further expand its manufacturing capabilities to be capable of supplying projected commercial quantities of Twirla. In 2018 Corium was acquired by Gurnet Holding Company, or GHC. Following completion of the transaction, Corium became a private company, wholly owned by GHC. Corium has announced that it plans to continue its operations in Grand Rapids, Michigan, where Twirla will be commercially manufactured.

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 the 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 site(s). 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.

In order to accommodate our anticipated commercial launch of Twirla, 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. We plan to complete the validation of the commercial manufacturing process for Twirla in the second half of 2020.

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 or a percent of the drug costs with products in the lower tiers having a lower co-pay. The Patient Protection and Affordable Care Act (ACA) was signed into law on March 23, 2010. As of August 1, 2011, female contraception was added to a list of preventive services covered by the ACA that would be provided without patient co-payment. The federal mandate applied to all new health insurance plans in all states from August 1, 2012.

Prior to May 2015, managed care plans individually interpreted the requirement for coverage of contraceptives under the ACA. Some plans 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 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. In May 2015, a clarification in the form of an FAQ was jointly issued by the applicable government agencies (HHS, DOL, and Treasury) which clarified the requirements for coverage of contraceptives under the ACA. The FAQ states that plans and issuers must cover without cost-sharing at least one form of contraception in each of the 18 methods the FDA has identified for women in its current Birth Control Guide. The patch is identified as a specific method in the FDA Birth Control Guide, and therefore insurers must cover at least one patch product with no cost-sharing to the patient. Because this clarifying guidance is applied for plan years (or in the individual market, policy years) beginning on or after 60 days from the date of publication of the FAQs, patients did not have the benefit of this clarification until their new plan year, which generally started in January 2016.

On January 20, 2017, the administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others. Congress also could consider subsequent legislation to repeal and replace elements of the ACA. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. While there is an injunction against the administration prohibiting it from implementing these rules, the ultimate outcome of that litigation, which is currently in front of the Supreme Court, cannot be predicted. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

Before the ACA was passed, many states had enacted contraceptive equity laws that required plans to treat contraceptives in the same way they covered other services. In addition, since the ACA was

passed, a number of states have enacted laws that basically codify in state legislation the ACA benefit rules (requiring all plans to cover, without cost-sharing, each of the 18 FDA-approved contraceptive methods). Federal law applies to all plans while state law applies to only individual plans and fully-insured group plans. Currently, 30 states and the District of Columbia require insurance plans to cover contraceptives, with a wide range of coverage and cost-sharing requirements, and exemptions among these mandates. If new federal regulations become effective the scope of contraceptive benefits for women would depend on the coverage policies and exemptions established by state laws. We will continue to monitor healthcare reform efforts and agency implementation.

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 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 Current Good Clinical Practices, or 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 FDA requirements for product manufacturing and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as the potential for completion of an FDA inspection of selected clinical sites to determine cGCP compliance; and
- FDA review and approval of the NDA.

Preclinical Studies and IND Submission

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

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 or conditions 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. In addition to the above traditional kinds of data required for the approval of an NDA, the 21st Century Cures Act provides for FDA acceptance of additional kinds of data such as such as patient experience data, real world evidence for already approved products, and, for appropriate indications sought through supplemental marketing applications, data summaries.

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 have obtained a waiver from the conduct of a PREA study.

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

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur. 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. Failure to submit the required information to ClinicalTrials.gov can result in monetary penalties. Marketing application applicants must also report certain investigator financial interests to the 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. Application resubmissions by the same applicant do not require a new application fee. Under the 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. These time periods may be extended by the FDA should an applicant submit new information to the agency during the course of the FDA's review of the marketing application. The time period is also only a goal and may not be met by the FDA.

The FDA conducts a preliminary review of all original 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 submitted again with the additional information and 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 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 the FDA's requirements for product manufacturing 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 a drug product 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 a marketing application 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 drug product and may require additional clinical or preclinical testing, or other information in order for the FDA to reconsider the application.

If an application receives a CRL, the applicant may resubmit the application, addressing all of the FDA-cited deficiencies, withdraw the application, or request the opportunity for a hearing. If the applicant resubmits the application, the application is subject to an initial FDA review. Within 30 days of receipt, the FDA will review a resubmission to determine whether it constitutes a complete response that addresses all deficiencies identified in a complete response letter. The agency then issues a letter to the applicant, stating whether the agency agrees that the resubmission is a complete response. If the FDA does not agree that the resubmission is a complete response, the review clock will not start until a complete response is received. If the agency agrees that the resubmission is a complete response, the FDA will classify the resubmission as either Class 1 or 2. The FDA aims to review Class 1 resubmissions within two months of receipt or Class 2 resubmissions within six months of receipt. Class 1 resubmissions are resubmissions of an NDA following a complete response letter that include minor updates or data reanalysis. Class 2 resubmissions include more complex or extensive updates to the NDA. As with the PDUFA timelines for original submissions, these are also subject to extension if the sponsor submits new information. Resubmitted applications may also be subject to FDA inspection of clinical and manufacturing sites, as well as review by FDA advisory committees. Following its review of a resubmitted NDA, the FDA may issue an approval letter or another CRL.

Even if an applicant resubmits with the required 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 certain aspects of a drug's safety and efficacy 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, submission of a supplemental application, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published

literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of an approved drug product 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 publication, 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 indicate 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 within a specified timeframe. 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 make an approval effective until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

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

submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against the FDA making an ANDA and 505(b)(2) NDA approval effective 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 the 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.

Recently, Congress, the Administration, and administrative agencies have taken certain measures to increase drug competition and thus, decrease drug prices. By example, in 2019 FDA introduced a proposed rule and draft guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market based terms to entities developing generic and similar drug products. This bill also included provisions on shared and individual REMS for generic drug products.

Combination Drug/Device Regulation

Twirla and our potential product candidates are considered to be drug-device combination products by the FDA. While our potential product candidates, as a whole, are subject to the NDA approval process, drug-device combination products require compliance with additional FDA regulations. For instance, drug-device combination products must comply with the drug cGMPs, as well as some of the device Quality System Regulations, or QSRs. These dual requirements will require additional effort, FDA reporting, and monetary expenditure to ensure that Twirla and our potential product candidates comply with all applicable regulatory requirements.

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 are also continuing, annual prescription drug program user fee requirements for any approved products. 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 FDA and state requirements for product manufacturing 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 FDA requirements for product manufacturing and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain FDA requirements for product manufacturing 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 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 reporting regarding drug samples. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, are required to label drug product with a product identifier and are required to keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures 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. Other persons and entities within the drug supply chain are also subject to Drug Quality and Security Act requirements.

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. 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 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.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False

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

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. For instance, the recently enacted California Consumer Privacy Act may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, 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 regulate price increases, 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, 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 Twirla and our other potential 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 potential 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 E.U. and other potentially significant markets for our potential 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 E.U. 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 potential 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 potential product candidates may not be considered medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development for a product candidate. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our potential product candidates or exclusion of our potential 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 potential 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 potential product candidates or exclusion of our potential 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 potential 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.

It is possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect sales of our potential product candidates. If third-party payors do not consider our potential product candidates to be cost-effective compared to other available therapies, they may not cover our potential 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 potential product candidates on a profitable basis.

In addition, 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 November 2015, the Bipartisan Budget Act was enacted into law, which, among other things, extended sequestration through 2025. 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 potential product candidates if they are approved.

On January 20, 2017, the then-new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices among others. Additionally, in October 2017, the Department of Health and Human Services, jointly with the Department of Labor and the Treasury, issued two interim rules outlining exemption processes for employers not wanting to offer contraceptive coverage based on their religious beliefs or sincerely held moral convictions. While there is an injunction against the administration prohibiting it from implementing these rules, the ultimate outcome of that litigation, which is currently in front of the Supreme Court, cannot be predicted. Congress also could consider subsequent legislation to repeal and replace elements of the ACA that are repealed. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

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

We currently have no plans to seek approval for Twirla outside of the United States. 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. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $9.9 million, $9.8 million, and $14.4 million for the years ended December 31, 2019, 2018, and 2017, respectively. In 2020, we expect to continue to incur research and development expenses as we refine our commercial manufacturing process.

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 potential product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our potential product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. 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 potential 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 potential 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 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 LNG, which is a synthetic progestin, and EE, 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 potential 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 potential product candidates, the release liner is removed by the user and discarded. The patch is then applied to the skin.

Eight U.S. patents, issuing from two 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 eight issued U.S. patents will expire November 22, 2020. Four will expire March 14, 2021. Two will expire July 10, 2028. The eighth will expire August 26, 2028.

U.S. Patent No. 7,045,145 is directed to the adhesive matrix of the transdermal delivery system used in Twirla 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 expire in March 2021. U.S. Patent No. 8,221,784 covers both Twirla and AG890. Foreign counterparts to these patents have been granted in China, Hong Kong, India, Israel, and Mexico. 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, or in an extended regimen without a rest interval for a selected number of weeks and expires November 22, 2020.

U.S. Patent Nos. 8,246,978, 8,747,888, and 9,050,348 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 July and August 2028. Foreign counterparts have been granted in Australia, Canada, China, Spain, France, Netherlands, Italy, UK, Ireland, Germany, Switzerland, Japan, Russia and New Zealand and one counterpart remains pending in India

U.S. Patent Nos. 9,198,876, 9,192,614, 9,198,919 and 9,198,920 and related patents and patent applications are directed to various novel dosing regimens, each of which employs transdermal delivery of contraceptive doses of EE and LNG during a "treatment interval" and transdermal delivery of low dose EE and low dose LNG during a "withdrawal interval". Foreign counterparts are pending or granted in Europe and Canada. We expect these patents will be relevant to two of the products in our pipeline, AG200-SP and AG200-ER, as well as other new potential regimens.

U.S. Patent No. 9,364,487 is directed to a composition and device for transdermal delivery of LNG for P-only therapy. The composition contains an anti-oxidant to protect the progestin against oxidative degradation caused by other components of the composition. Foreign counterparts are pending or

granted in Canada, Europe, India, Japan and Mexico. We expect this patent to be relevant to at least one product in our pipeline, AG890.

We have patent applications pending in the United States and certain foreign jurisdictions directed to novel formulations and methods designed to improve efficacy and modulate side effects of administration, as well as to provide personalized dosing based on body weight or BMI. We also have a pending United States patent application directed to packaging for transdermal systems containing certain skin permeation enhancers.

Regulatory Exclusivity

Our NDA for Twirla was submitted under Section 505(b)(2) of the FDCA. Even though Twirla utilizes API that were previously approved in the United States, Twirla utilizes LNG in a new dosage form, specifically a transdermal patch, and we provided new clinical data essential to approval in our NDA to establish the safety and efficacy of Twirla. Therefore, we received three years of U.S. marketing exclusivity for Twirla under the Hatch Waxman Act. The exclusivity prohibits 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 is not the first approval of the API.

Employees

As of December 31, 2019, we had 15 full time employees, including six in research and development and nine 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 is 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 a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act. Since the aggregate market value of our voting stock held by non-affiliates was less than $75 million on June 28, 2019, we are a non-accelerated filer under the rules of the SEC, and an auditor attestation report over Internal Controls over Financial Reporting does not need to be included in the 2019 Form 10-K.

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 Commercialization of Twirla

We are significantly dependent on the commercial success of Twirla, our only approved product. If we are unable to successfully commercialize Twirla, our business, financial condition, results of operations, and prospects and value of our common stock will be materially adversely affected.

Twirla will be the first product that we commercialize. The rest of our pipeline of potential product candidates are in earlier stages of clinical development and will require additional clinical studies and product development and funding in order to advance towards commercialization, which could take considerable time. In addition, we will require additional capital for the validation of our commercial manufacturing process and commercial launch of Twirla. We will not be able to commercially launch Twirla until validation is complete and we may not be successful in completing validation within expected timelines or at all. We will also require capital to develop and initiate post-marketing studies of Twirla. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Twirla. Potential prescribers of Twirla include physicians, nurse practitioners, or NPs, physician's assistants, or PAs, and pharmacists. Registered Pharmacists are authorized to prescribe contraceptives in some states, and other states have pending legislation that would allow pharmacists to prescribe contraceptives. If Twirla does not gain an adequate level of acceptance among prescribers, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Twirla by prescribers, 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 Twirla in relation to alternative treatments;
- Relative convenience and ease of administration of Twirla;
- Availability of adequate coverage or reimbursement of Twirla 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 Twirla;
- Cost of Twirla in relation to alternative treatments, including generic products;
- Extent and strength of our third-party manufacturer and supplier support and ability to meet our market demand;
- Extent and strength of our marketing and distribution support;
- Limitations, warnings, or contraindications contained in Twirla's FDA approved labeling, including safety warnings and precautions, contraindications and limitations on the use of Twirla for women based on BMI. By example, Twirla's label includes the class-wide black box warning, contraindications, and warnings and precautions applicable to all combined hormonal contraceptives, or CHCs. Twirla also includes a black box warning that Twirla is contraindicated in women with a BMI $\geq$ 30 kg/m^2, and that compared to women with a lower BMI, women with a BMI $\geq$ 30 kg/m^2 had reduced effectiveness and may have a higher risk for venous

thromboembolic events. Twirla's label also contains a limitation of use to consider Twirla's reduced effectiveness in women with a BMI of ≥25 to ≤30 kg/m^2 before prescribing.

For example, prescribers 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 advantages over other treatment options, because no adequate head-to-head trials comparing the safety and efficacy of Twirla to the competing approved patch or other contraceptive products have been conducted, we cannot make claims that Twirla is safer or more effective than the currently approved patch product, or other contraceptive products, without conducting a supportive head-to-head postmarketing study. Moreover, we will not be able to make any other Twirla marketing or promotional claims to the extent that they are inconsistent with the Twirla FDA-approved label or are not otherwise supported. The availability of numerous inexpensive generic forms of contraceptive products may also limit acceptance of Twirla among prescribers, patients and third-party payors. If Twirla does not achieve an adequate level of acceptance among prescribers, patients and third-party payors, we may not generate significant product revenues or become profitable, and the value of our common stock may suffer.

We may not be able to successfully commercialize Twirla, and the revenue that we generate from its sales, if any, may be limited.

The commercial success of Twirla will depend upon the contraceptive market landscape as well as acceptance and uptake of Twirla by prescribers, 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 mass tort lawsuits due to adverse effects;
- Price pressures from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;
- The proportion of the contraceptive market comprised of generic products could continue to increase, making the 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;
- Healthcare reform activities, including, without limitation, the repeal, reform or replacement 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 effects on pharmaceutical coverage, reimbursement and pricing, could limit our revenue;
- Access to the prescriber universe, particularly obstetrics and gynecology physicians, could be limited, decreasing our ability to promote Twirla efficiently; and
- Our ability to access pharmacists in states where they are authorized by law to prescribe contraceptives could be limited, decreasing our ability to promote Twirla.

The degree of acceptance and uptake of Twirla by prescribers, 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, warnings, or contraindications contained in Twirla's FDA approved labeling, including safety warnings and precautions, contraindications, and limitations on the use of Twirla for women based on BMI;
- Acceptability to patients of the appearance and feel of Twirla;
- Willingness of prescribers to prescribe a contraceptive patch based on the labeling and prior experience with the generic contraceptive patch already on the market;
- Willingness of prescribers to prescribe a contraceptive patch in light of safety issues and restrictive labeling of the generic contraceptive patch already on the market;
- 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, we may face additional generic or other drug product competition sooner than we anticipate for Twirla or our potential product candidates, which would potentially limit their commercial success. We believe that Twirla is eligible for three years of FDA marketing exclusivity for Twirla. The FDCA provides a period of three years of marketing exclusivity for 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 Twirla. We, however, may not receive the three-year exclusivity for them, and, even if we do, it may not adequately protect us from competition. Competition that Twirla and our potential product candidates may face from generic or similar versions of the same or similar products 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 Twirla or our potential product candidates.

If Twirla does not achieve an adequate level of acceptance by prescribers, 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 prescribers, 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 be able to generate sufficient revenue or sustain profitability. Our ability to generate sufficient revenue from Twirla will also be dependent on our ability to support the commercial demand for Twirla and we cannot assure you that we along with our manufacturing partner Corium will be able to complete validation of our commercial manufacturing successfully and in a timely manner, and, ultimately, to commercially market Twirla. We also cannot assure that we and Corium will be able to manufacture sufficient quantities of Twirla in order to meet commercial demand.

It will be difficult for us to profitably sell Twirla if coverage and reimbursement for such product is limited.

Market acceptance and sales of Twirla 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 and, if coverage is available, we cannot be sure of the level of reimbursement. Even when a payor determines that a product is eligible for reimbursement, the payor may set a reimbursement rate that is too low to support a profitable sales price for the product. Subsequent approvals of competitive products could result in a detrimental change to the reimbursement of our products. Reimbursement may impact the demand for, or the price of, Twirla. 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. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize Twirla, which would adversely impact our business, financial condition, results of operations and prospects and the value of our common stock.

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

At present, we have no sales personnel and a limited number of marketing personnel. Initially, we do not plan to establish our own sales force. Rather, we plan to engage a contract sales organization in the United States and, depending on our available capital resources, we plan to also hire a limited number of additional marketing personnel in the second and third quarters of 2020. At the time of our anticipated commercial launch of Twirla, 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 marketing capabilities 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 in the United States include:

- Our ability to obtain additional capital;
- Our or our contractor's 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 prescribers 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, 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.

If estimates of the size of the potential market for Twirla are overstated or data we have used to identify physicians is inaccurate, our ability to earn revenue to support our business could be materially adversely affected.

We have relied on a number of external sources, as well as market research funded by us and internal analyses and calculations, to estimate the potential market opportunity for Twirla in the United States. We have not independently verified the externally sourced information used to develop the estimates for the potential market for Twirla, and their accuracy and completeness cannot be assured. Similarly, our internal analyses and calculations are based upon analysis of the current and expected future U.S. contraceptive market and management's understanding and assessment of numerous inputs and market conditions, including, but not limited to, the addressable market segment for combined hormonal contraceptives and the reimbursement status of contraceptives under the federal Affordable Care Act and similar state laws. These understandings and assessments necessarily require assumptions subject to significant judgment and may prove to be inaccurate. As a result, our estimates of the size of the potential market for Twirla could prove to be overstated, perhaps materially.

In addition, we are relying on third party data to identify the healthcare providers who prescribe contraception in the U.S. and to determine how to deploy resources to market to those healthcare providers; however, we may not be marketing to the appropriate physicians and may therefore be limiting our market opportunity.

We may develop estimates with respect to market opportunities for potential product candidates in the future, and such estimates would be subject to similar risks. Even if we obtain regulatory approval for one or more potential product candidates, we may be unable to commercialize the product on a scale sufficient to generate significant revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects and the value of our common stock.

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

The proportion of the U.S. market that is made up of generic products has been increasing over time. For example, in 2005, generic contraceptive products held 49% of prescription volume and 36% of sales and, by 2019, those values had risen to 88% and 43%, respectively. Recently, Congress and the FDA have taken steps to increase generic competition in the market. If this trend continues, it may be more difficult to introduce Twirla 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 branded generic version of the Ortho Evra product by Mylan Inc. in April 2014, and the subsequent discontinuation of distribution of Ortho Evra in October 2014 by Janssen we may have to take additional measures in order to be competitive and gain market share. For example, 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.

Prescribers, patients and payors may not adopt a new contraceptive patch due to concerns based upon the prior experience with or perception of the previously marketed contraceptive patch and its currently marketed generic equivalent product.

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, the manufacturer of Evra and the FDA began receiving reports of thrombotic and thromboembolic events.
- 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 boxed 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 boxed warning and bolded warning in the Evra label.

- The approval of a generic equivalent to Evra, Xulane was announced by Mylan Inc. in April 2014. Subsequently, in October 2014, Janssen discontinued distribution of Evra and currently over 99% of patch prescriptions are filled with the generic.

We have conducted pharmacokinetic studies of Twirla to demonstrate that it delivers a daily EE dose of approximately 30 micrograms, which is less than that delivered by Xulane, according to its FDA approved label. However, because none of our completed Phase 3 clinical trials studied Twirla in a head-to-head comparison with Xulane, we will not be able to make comparative claims regarding the EE exposure, safety, or efficacy of Twirla as compared to Xulane without conducting a supportive head-to-head post-marketing study., As a result, uptake and usage of Twirla and our related revenues could ultimately be limited.

Twirla could develop unexpected safety, efficacy or quality concerns, which would likely have a material adverse effect on us.

Twirla was approved in the U.S. based on the SECURE clinical trial, in which patients were enrolled for 13 cycles of treatment. Twirla will now be used by larger numbers of patients, potentially for longer periods of time, and we and others (including regulatory agencies and private payors) will endeavor to collect extensive information on the efficacy and safety of Twirla by monitoring its use in the marketplace. In addition, we will endeavor to conduct a long-term post marketing safety study required by the FDA to compare the risks for venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of oral combined hormonal contraceptives (CHCs) and new users of Xulane in U.S. women of reproductive age. Further, we may conduct additional trials in connection with lifecycle management programs for Twirla. New safety or efficacy data from both market surveillance and our post-marketing clinical trials may result in negative consequences including:

- Modification to product labeling or promotional statements, such as additional boxed or other warnings contraindications, or limitations, or the issuance of "Dear Doctor Letters" or similar communications to healthcare professionals or the public regarding safety or efficacy concerns;
- Imposition of additional post-marketing clinical trial requirements, distribution restrictions or other risk management measures, such as a risk evaluation and mitigation strategy, REMS, which could include elements to assure safe use;
- Suspension or withdrawal of regulatory approval;
- Suspensions or termination of ongoing clinical trials or refusal by regulators to approve pending marketing applications or supplements to approved applications;
- Suspension of, or imposition of restrictions on, our operations, including costly new manufacturing requirements with respect to Twirla;
- Costly and time-consuming corrective actions; and
- Voluntary or mandatory product recalls or withdrawals from the market and costly product liability claims.

Furthermore, the discovery of significant problems with a product similar to Twirla that implicate (or are perceived to implicate) the entire class of products could have an adverse impact on our ability to commercialize Twirla. Any of these circumstances could reduce Twirla's market acceptance and would inhibit or delay our ability to commercialize Twirla or gain and/or sustain market share, any of which would adversely affect sales of Twirla.

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 we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Our potential competitors include, but are not limited to, large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. These companies include Merck & Co., Inc., or Merck, which markets Nuvaring®, TherapeuticsMD, Inc., or TherapeuticsMD, which has licensed and will market Annovera®, a recently approved contraceptive ring, Allergan, Inc., or Allergan, which markets several branded and generic contraceptives including Minastrin® 24, LoLoestrin®, and Taytulla®, Bayer AG, or Bayer, which markets Beyaz®, Yaz®, Yasmin®, and Natazia®, and Mylan N.V., 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, Inc.

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. Bayer entered into a license and distribution agreement for the sale of this contraceptive patch in Europe with Gedeon Richter Ltd. Other companies that have new hormonal contraceptive product candidates in various stages of development include Allergan (progestin-only vaginal ring for which they received a CRL from the FDA), The Population Council in collaboration with Antares Pharma, Inc. (transdermal gel contraceptive in Phase 2), Mithra Pharmaceuticals SA (combination oral contraceptive in Phase 3), and Panterhei Bioscience (combination oral contraceptive in Phase 2).

Sales of Twirla 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 Twirla and our potential product candidates, 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 2018, three companies generated about 95% of all revenues from drug distribution in the United States, and in 2019, the top five chain pharmacy companies owned about 35% 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.

Existing and future legislation may increase the difficulty and cost for us 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 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 our ability to market of Twirla may be.

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 the healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional healthcare policy reforms. The ACA, among other things, increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs, extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, addressed new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are line extension products and expanded the 340B drug discount program (excluding orphan drugs) to other entities. Further, the ACA imposed a significant annual tax on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with regard to healthcare practitioners.

Of particular relevance to our business is the ACA requirement that all health plans, with limited exceptions, cover certain preventive services for women with no cost-sharing, which means no deductible, no co-insurance and no co-payments by the patient. Contraceptive methods and counseling, including all FDA-approved contraceptive methods as prescribed, are included in the ACA mandate, and this has come to be known as the "contraceptive mandate." Under the ACA, payors are only required to cover one favored product within each contraceptive "method" without imposing any cost-sharing obligations on the patient. For example, the introduction of a generic contraceptive patch product with a price that will likely be lower than the price of Twirla makes it less clear that Twirla would have a preferred position, such as coverage without a co-insurance payment, under the ACA contraceptive mandate. Other products within the same method may also be covered, but payors are allowed to use reasonable medical management techniques, such as the application of cost-sharing obligations. An amendment was issued that provided an exemption to the contraceptive mandate for group health plans established or maintained by religious employers. However, the contraceptive mandate has remained controversial, with several legal challenges filed around the country. In June 2014, the U.S. Supreme Court ruled that owners of certain private companies can object to the contraceptive mandate on religious grounds and in November 2015, the Court agreed to hear arguments from non-profit organizations requesting similar treatment. In October 2017, the U.S. Department of Health and Human Services announced it will seek to issue regulations that will allow all companies to qualify for the exemption from the contraceptive mandate on the basis of religious and moral grounds. While there is an injunction against the administration prohibiting it from implementing these rules, the ultimate outcome of that litigation, which is currently in front of the Supreme Court, cannot be predicted. The ACA appears likely to continue to apply pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Further, on January 20, 2017, the current administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, among others. There are several proposals to reform the federal healthcare laws being advocated and it is still unclear whether such reform efforts will succeed and if so, which proposals will ultimately be successful. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business.

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 in funding 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, 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 Twirla and our potential product candidates and reduce our profitability.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, are required to label the drug product with a product identifier and are required to keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers is required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufacturers 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.

Other measures have also been taken by Congress, the Administration, and administrative agencies to increase drug competition and thus, decrease drug prices. By example, in 2019 FDA introduced a proposed rule and draft guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA approved products to provide sufficient quantities of drug product on commercially reasonable market based terms to entities developing generic and similar drug products. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

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

Our ability to successfully market Twirla will depend in part on the level of coverage and reimbursement that government authorities, private health insurers and other organizations provide for Twirla and contraceptives in general. Countries in which Twirla is 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 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.

We may never seek or receive marketing approval for or commercialize Twirla outside the United States.

In order to market Twirla 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 Twirla. The time required to obtain approval in other countries might differ from and be longer than the time 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 may not exist in other countries. In territories where data is not freely available, we may not have the ability to commercialize Twirla, or any products approved in the future, without negotiating the 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 the advancement of our products in such countries. Further, product labeling requirements outside the United States may be different and inconsistent with the U.S. labeling, potentially negatively affecting our ability to market in countries outside the United States.

Marketing approval in one country does not ensure marketing approval in another, but 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 marketing potential of our products will be harmed.

Risks Related to Our Financial Position and Need for Capital

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. Management has concluded that these factors raise substantial doubt about our ability to continue as a going concern.

We have incurred losses in each year since our inception in December 1997. Our net loss was $18.6 million, $19.8 million and $28.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $260.4 million. In February 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, or Perceptive, for a senior secured term loan facility of up to $35 million, which we refer to as the Perceptive Credit Agreement. We believe that our cash and cash equivalents as of December 31, 2019, along with the proceeds of the Perceptive Credit Agreement we have received to date, will be sufficient to meet our projected operating requirements through the end of 2020. They will not be sufficient to fund our current and planned operations through the 12 months following the date

on which this Annual Report on Form 10-K is filed, which raises substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future.

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 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 we will need to incur additional expenses as we complete the qualification and validation of our commercial manufacturing process, initiate pre-launch commercial activities, commercially launch Twirla, advance our other potential product candidates and expand our research and development programs. We will require additional capital to fund our operating needs beyond 2020, including among other items, the completion of our commercial plan for Twirla, which primarily includes validation of our commercial manufacturing process, as well as the commercial launch of Twirla and advancing the development of our other potential product candidates. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. 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 potential product candidates will also require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

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. Any 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 additional capital. We are significantly dependent on the success of Twirla, and if we do not achieve the commercial success of Twirla and/or are unable to obtain additional funding, we will need to reassess our operating capital needs and may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

We have never been profitable. Currently, we have no products available for commercial sale, no source of revenue pending the commercial launch of Twirla, 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 currently available for commercial sale, and will not have any products available for sale until the commercial launch of Twirla, which we currently anticipate will commence in the fourth quarter of 2020. To date, we have not generated any revenue from product sales. Even if we are able to commercialize Twirla or any other potential 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:

- Obtain additional capital for the commercial scale-up of the Twirla manufacturing process and commercial launch of Twirla as well as advancing the development or our other potential product candidates;
- Set an acceptable price for Twirla and our other potential product candidates, if approved, and obtain adequate coverage and reimbursement from third party payors;
- Obtain commercial quantities of Twirla and our other potential product candidates, if approved, at acceptable cost levels from our third-party manufacturer;

- Successfully market and sell Twirla and our other potential product candidates, if approved, in the United States and abroad; and
- Successfully receive regulatory approval for our other potential product candidates.

In addition, because of the numerous risks and uncertainties associated with product commercialization and 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 and resources if we are required to provide increased rebates to managed care payors, experience set-backs in the validation of our commercial manufacturing process, we need to increase our manufacturing capacity sooner than planned, experience disruptions in our manufacturing capabilities, or need to alter our marketing strategy. We anticipate incurring significant costs associated with the commercial launch of Twirla and our other potential product candidates, if approved.

Our ability to become and remain profitable depends on our ability to generate revenue in excess of our increasing costs. Even if we are able to generate revenues from the sale of Twirla and our other potential product candidates, 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 additional 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.

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.

In February 2020, we entered into the Perceptive Credit Agreement for a senior secured term loan facility of up to $35.0 million. A first tranche of $5 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA. Another $15 million tranche will be available upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

The Perceptive Credit Agreement subjects us to various customary affirmative and negative 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 Perceptive Credit Agreement also subjects us to financial covenants in respect of minimum liquidity and minimum product revenue.

The loans provided under the Perceptive Credit Agreement are secured by substantially all of our property. We are currently required to make interest-only payments through February 2023. Loans under the Perceptive Credit Agreement currently bear interest at rate of 10.25% per annum plus one-month LIBOR, and mature on February 10, 2024.

The Credit Agreement contains certain customary Events of Default, which include, among others, non-payment of principal, violation of covenants, inaccuracy of representations and warranties,

bankruptcy and insolvency events, material judgments, certain regulatory-related events and events constituting a Change of Control (as defined in the Credit Agreement). 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 potential 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. Perceptive 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 substantially all of our 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 commercialize Twirla or to complete the development and commercialization of our other potential product candidates.

Our operations have consumed substantial amounts of cash since inception. From our inception to December 31, 2019, we have cumulative net cash flows used by operating activities of $227.3 million. We will need to obtain additional capital to fund our future operations, including the commercialization of Twirla. We will need to obtain additional financing to develop and commercialize our other potential product candidates 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:

- Our ability to successfully commercialize Twirla and our other potential product candidates, if approved;
- Our ability to have commercial product successfully manufactured consistent with FDA regulations;
- Amount of sales and other revenues from Twirla and our other potential product candidates that we may commercialize, if any, including the selling prices for such products and the availability of adequate third-party coverage and reimbursement;
- Sales and marketing costs associated with commercializing Twirla and our other potential product candidates, if approved, including the cost and timing of expanding our marketing and sales capabilities;
- Time and cost necessary to obtain regulatory approvals for our other potential product candidates that may be required by regulatory authorities;
- Progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our ongoing, planned and any clinical trials;
- 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 potential product candidates;
- Time and cost necessary to respond to technological and market developments;
- Costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- Costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish;
- Costs associated with the expansion of our commercial manufacturing process for Twirla and/or the establishment of a backup supplier;
- Costs associated with the hiring of new employees and our contract sales force; and
- Costs associated with the leasing of additional office space.

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 our commercialization efforts or one or more of our research or development programs. 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 potential product candidates or to grant licenses on terms that may not be favorable to us.

Our planned timeline for the commercial launch of Twirla and our ability to fund our operations through the period of time necessary to successfully commercialize Twirla could be adversely affected based on our inability to timely and successfully complete the validation of our commercial manufacturing process, the failure of Twirla to gain acceptance in the marketplace, our inability to successfully compete with other contraceptive products and the need to provide higher rebates in order to gain a competitive formulary status. We may not be able to obtain sufficient additional funding to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms, or we are unable to enter into strategic collaborations, we then may be unable to complete the commercialization of Twirla and may also be required to further cut operating costs, delay, reduce or eliminate our research and development programs or future commercialization efforts or even terminate our operations, which may involve seeking bankruptcy protection. 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. If we choose to accelerate elements of our commercial plan or we encounter any unforeseen events that affect our business plan, we may choose to raise additional funds to provide us with additional working capital. Our inability to obtain additional funding when we need it could seriously harm our business and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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.

Risks Relating to Maintaining Regulatory Compliance and Approval of Twirla

We remain subject to substantial ongoing regulatory requirements related to Twirla, and failure to comply with these requirements could lead to penalties, including withdrawal from the market, suspension, or withdrawal of product approval.

Twirla is 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, including ongoing requirements for costly post-marketing studies, including Phase 4 clinical trials or post-market surveillance. For example, as part of the FDA's approval of Twirla, the FDA has required a long-term post-marketing safety study to assess and describe the risks of Twirla, including the risk of VTE and ATE compared to oral combined hormonal contraceptives and Xulane. This study is similar to one recently required by FDA for another contraceptive product. We will also conduct a second small post-marketing study, required by FDA, to assess Twirla's residual drug content, strength, and adhesion. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. Failure to comply with post-market study requirements can also result in enforcement action or FDA removal of the product from the market.

Other post-approval 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 routine inspections by the FDA and other regulatory authorities for compliance with the FDA's manufacturing requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we are found to be noncompliant with applicable requirements, 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, requests for a recall, refusal to allow the import or export of the product, criminal or civil penalties, injunction against or restriction of product manufacture or distribution, consent decrees, disgorgement, restitution, clinical holds or terminations of clinical trials, FDA debarment, debarment from government contracts or refusal of orders under existing contracts, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

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

With respect to sales and marketing activities by us or any future collaborative partner, advertising and promotional materials must comply with the FDA's rules in addition to other applicable federal and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act and is subject to certain requirements. 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 efforts. 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, our product labeling, advertising and promotional materials for Twirla will 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. 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 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.

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

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 products 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. 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 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, such as the California Consumer Privacy Act, 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.

Compliance with these and other federal and state laws applicable to the sale, marketing, and distribution of commercial drug products will require that we expend time and financial resources to maintain compliance. Additionally, 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, 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 provides 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 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 Manufacturing and Our Reliance on Third Parties

We have no manufacturing capacity and anticipate continued reliance on Corium, our third-party manufacturer, for the commercialization of Twirla and development of our potential product candidates. We may not have or be able to obtain sufficient quantities of Twirla or our potential product candidates to meet our required supply for commercialization or clinical trials, which would materially harm our business.

Corium is a biopharmaceutical company that focuses on the development, manufacture, and commercialization of specialty transdermal products. In addition to partnering with other companies to manufacture transdermal products, Corium also engages in the research and development of its own proprietary transdermal drug delivery products. We rely on Corium, our third-party manufacturer, to produce commercial supplies and samples of Twirla. We also plan to rely on them for clinical and commercial supplies and samples of our potential product candidates, if approved. We do not own or operate, and have no plans to establish, any manufacturing facilities for Twirla or our potential product candidates. We lack the resources and the capabilities to manufacture Twirla or any of our potential product candidates on a clinical or commercial scale.

As a third-party manufacturer, Corium's business operations are completely beyond our control, and we have no influence over whether Corium changes its management or its business operations or discontinues them entirely. For example, in 2018 Corium was acquired by Gurnet Holding Company, or GHC. Following completion of the transaction, Corium became a private company, wholly owned by GHC. Corium has announced that it plans to continue its operations in Grand Rapids, Michigan, where commercial supplies of Twirla are being manufactured.

Furthermore, we do not control the manufacturing process of Twirla, and are completely dependent on Corium for compliance with the FDA's manufacturing regulatory requirements for the manufacture of Twirla, our potential product candidates and our other future products, if and when approved. As a manufacturer, Corium or other contract manufacturers that we may use are subject to routine inspection by regulatory authorities, including FDA. 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, they may receive adverse inspectional findings, may need to undertake costly and time consuming corrective actions, and may not be able to maintain regulatory approval for their manufacturing facilities.

In addition, while the contracts with our manufacturers contain provisions to help ensure that quality standards and compliance with laws and regulations are maintained, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and

qualified personnel. If in the future, the FDA withdraws its approval of Corium's facilities for the manufacture of Twirla, or if Corium experiences quality or other regulatory issues, we may need to find alternative manufacturing facilities that would also require FDA approval, which would significantly impact our ability to develop and sustain our market share of Twirla and to develop, and obtain, regulatory approval for and market our potential 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, we may be subject to regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of product or investigational approvals, clinical holds or termination of clinical trials, refusals to approve pending applications, 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 commercial supplies in adequate quantity and quality, our commercialization of Twirla could be delayed. An inability of our contract manufacturer to produce supplies in adequate quantity and quality of our Twirla and our potential product candidates could also delay our ability to conduct clinical trials. This may adversely impact our ability to fulfil our post-marketing study requirements for Twirla and obtain regulatory approval of our potential product candidates.

The machinery and process 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 and the processes in a timely manner and successfully produce validation batches, our ability to launch and commercialize Twirla will be compromised and we could require additional capital to complete the validation process. 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 potential 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 potential 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 and the development of our potential product candidates.

Although we have manufacturing agreements with Corium for the 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. Corium's failure to timely obtain, or a disruption in the supply of, these raw materials could lead to an inability to adequately supply the commercial market with finished product of Twirla and in turn adversely affect our business.

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 potential product candidates could limit our ability to meet clinical and commercial demand for Twirla.

In addition, in the event Twirla 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 and processes.

Reliance on a third-party manufacturer subjects us to risks that would not affect us if we manufactured Twirla and our potential product candidates ourselves, including:

- Reliance on the third party for regulatory compliance and quality assurance;
- Reduced control over the manufacturing process for Twirla and our potential 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;
- The inability to identify an alternate manufacturer, or if a manufacturer is identified, to secure services on commercially reasonably terms; and
- The disruption and costs associated with changing suppliers.

Twirla and our potential 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 in compliance with the FDA's manufacturing 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 products or potential product candidates for any reason, we likely would experience delays in obtaining sufficient quantities of our products or potential product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify alternative suppliers. If for any reason we are unable to obtain adequate supplies of our products or potential product candidates or the components used to manufacture them, it will be more difficult for us to develop our potential product candidates and compete effectively.

Our third-party manufacturer is subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to Twirla and our potential 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 Twirla and our potential 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 commercialize Twirla or develop our potential product candidates.

We, through our manufacturing partner Corium, rely on a number of third parties for the supply of active ingredients, other raw materials and laboratory services for the commercialization or Twirla and supply of our potential product candidates. Our ability to commercialize Twirla and to develop our potential product candidates depends, in part, on Corium's ability to successfully obtain the components used to manufacture Twirla and our potential product candidates, in accordance with regulatory

requirements and in sufficient quantities for commercialization and clinical testing meeting the applicable quality standards. If Corium fails to develop and maintain supply relationships with these third parties, or if Corium is unable to develop new relationships to replace any existing relationships that are lost, we may be unable to commercialize Twirla or to continue to develop our potential product candidates. Moreover, these third parties will be subject to FDA inspection. If these third parties do not comply with the FDA's regulatory requirements, we may not be able to maintain approval for Twirla or receive or maintain approval for any of our potential product candidates, and we may be subject to other regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of investigational approvals, clinical holds, or termination of clinical trials, refusals to approve pending applications, 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.

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 the commercialization of Twirla or the development of our potential product candidates, indefinitely.

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

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

Corium's facilities used for the manufacture of Twirla and our potential product candidates must be maintained in a manner compliant with the FDA's manufacturing 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 potential 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, non-approval of marketing applications, clinical holds or termination of clinical trials, 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 potential product candidates and substantial

additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues. There is further no guarantee that the FDA would approve these alternative facilities.

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

We currently rely and plan to continue to rely on CROs and clinical trial sites for most aspects of our post-marketing study and any other clinical trials of our potential product candidates, such as trial conduct, data management, statistical analysis and electronic compilation of our FDA submission. We may enter into agreements with additional CROs and clinical trial sites 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 and clinical trial sites involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and clinical trial sites and the time the CRO and sites commences work. As a result, delays may occur, which may materially impact our ability to meet our desired post-marketing and clinical development timelines and ultimately have a material adverse impact on the commercialization of Twirla, our ability to maintain our marketing authorization for Twirla, our operating results, financial condition or future prospects. For example, as part of Twirla's approval, the FDA is requiring that we conduct a post-marketing study comparing the risks for venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of oral combined hormonal contraceptives (CHCs) and new users of Xulane in U.S. women of reproductive age. The FDA has also required a second small post-marketing study to assess Twirla's residual drug content, strength, and adhesion. We plan to engage the services of a CRO to design, enroll, and complete this study, which will likely involve thousands of subjects and hundreds of clinical trial sites and will require substantial time and resources. If the CRO cannot enroll subjects and complete the trial in a timely manner, we may be unable to complete the study required by the FDA and subsequently may lose our marketing authorization for Twirla or be subject to other enforcement actions, and be forced to suspend commercial activities regarding the product.

As CROs and clinical investigators 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 products and potential product candidates in clinical trials, which include requirements related to the conduct of the study, subject informed consent, and IRB approval. Regulatory authorities enforce these cGCPs through routine inspections of trial sponsors, principal investigators and trial sites. Although we may rely on third parties for the execution of our trials, we are nevertheless responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs and clinical trial sites does not relieve us of our regulatory responsibilities. If we, any of our CROs, or clinical trial sites 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 for potential product candidates in development, or to perform additional post marketing studies for approved products or determine that data from the post marketing study is not sufficient to support maintaining marketing authorization for the product at issue. We cannot assure you that, upon

inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or post marketing studies complies with cGCP regulations.

In addition, our clinical trials must be conducted with product and potential product candidates' materials produced in compliance with the FDA's manufacturing regulations. Our failure to comply with these regulations may require us to discontinue or repeat clinical trials, which would delay the regulatory approval process for our potential product candidates or impact our ability to meet our post-market study requirements. If the CROs or clinical trial sites we engage do not successfully carry out their contractual duties or obligations, conduct the clinical trials in accordance with all regulatory requirements and the applicable protocols, 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, we may not be able to obtain marketing approval for or successfully commercialize our potential product candidates, or we may not be able to meet our post-market study requirements. 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 of clinical trials, non-approval of marketing applications, criminal and civil penalties, including imprisonment, injunction against manufacture or distribution and debarment. As a result, our financial results and the commercial prospects for Twirla or our potential 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 commercialize Twirla and to develop and commercialize our potential product candidates.

We may seek partnerships, collaborations and other strategic transactions to maximize the commercial potential of Twirla, our potential 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 potential 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. Collaborators, also, may not comply with the applicable regulatory requirements, which may subject them or us to enforcement actions.

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

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

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

We do not currently have the infrastructure necessary for distributing pharmaceutical products. We intend to contract with a third-party logistics wholesaler 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 third party logistics providers s could negatively impact the distribution of Twirla and our potential product candidates, 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 Twirla and of our potential product candidates, 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 and we and our distributors will be required to hold state licenses in the States to which Twirla or any of our potential product candidates, if approved, are distributed. If we or our distributors do not comply with the applicable regulatory requirements, we could be exposed to potential enforcement actions and product distribution may be interrupted or discontinued.

We may rely on third parties to perform many essential services for any products that we commercialize, including services related to government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our potential product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to Twirla, key aspects of which will be out of our direct control. These service providers may provide key services related to customer service, accounts receivable management, and cash collection. If we retain a service provider, we would substantially rely on it as well as other third-party providers that perform services for us. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage third parties to perform various other services for us relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding Twirla and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, we could be subject to regulatory sanctions.

We may further contract with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or errors in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

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 Twirla and our potential 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 the term of patent protection that we may have for our potential product candidates. Even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our potential product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product and potential product candidates and potential products may prevent us from obtaining or enforcing patents relating to this product and potential product candidates and potential products, including without limitation transdermal delivery systems and methods of using such transdermal delivery systems. Our product and potential product candidates contain generically available active pharmaceutical ingredients. As a result, new chemical entity patents directed to the active pharmaceutical ingredients in our product and potential product candidates, which are generally believed to offer the strongest form of patent protection, are not available for our potential 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 Twirla and our potential 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 Twirla or our potential product candidates using the same active pharmaceutical ingredients;
- There can be no assurance that the term of patent protection will be long enough for our company to realize sufficient economic value under the patents following commercialization of Twirla or our potential product candidates, if approved;
- 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 Twirla or our other potential product candidates;
- Our patents may face paragraph IV challenges from potential generic or 505(b)(2) applicants, asserting that our applicable patents are invalid, unenforceable, 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 Twirla or our potential 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 one or more patent claims;
- 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, Twirla or our potential product candidates does not infringe our patents; and
- Our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

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, similar or strength modified versions of any approved products by submitting abbreviated new drug or 505(b)(2) NDA 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 Twirla or our potential 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, and commercial launch of new products, patents protecting any approved product we may have might expire or be held invalid or unenforceable before our company can realize sufficient economic value following commercialization.

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 Twirla or our potential 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, that we will obtain sufficient claim scope or term in those patents to prevent a

third party from competing successfully with Twirla or our potential product candidates, or that, even if our patents are found to be valid, enforceable, and infringed, a legal tribunal would enjoin infringing activity.

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

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology, Twirla and potential 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 are 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 reexamination, post-grant review, *inter partes* review, or derivation 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, as well as the courts' treatment of any appeals to related proceedings, remain unclear. 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 Twirla or our potential product candidates, our competitive position would be adversely affected.

We may infringe the intellectual property rights of others, which may prevent or delay our commercialization and product development efforts or increase the costs of commercializing Twirla or our potential product candidates, 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 Twirla or our current or future potential 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 Twirla or our current or future potential product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that Twirla or our current or future potential 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 Twirla or our potential 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, potential product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability 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, potential product candidates, or their use, the holders of any of these patents may be able to block our ability to commercialize

Twirla or our potential 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 or potential product candidates or lead to prohibition of the manufacture or sale of our product or potential 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 or potential product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Many of our employees, consultants and contractors were previously employed at or engaged by biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any 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 Twirla and our potential 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, previously took steps to increase the public disclosure of information regarding FDA-regulated products, including information that we may consider to be trade secrets or other proprietary information. It is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

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

We may be required to initiate litigation to enforce or defend our intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the 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 in the United States and other jurisdictions could face other challenges, such as derivation or interference proceedings, opposition proceedings, *inter partes* review, reexamination proceedings, third party submissions of prior art, and other forms of post-grant challenges. In the United States, for example, post-grant review, which is similar to opposition proceedings available in many countries other than the U.S., was newly established by the Leahy-Smith Act. 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 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 Potential Product Candidates

If we fail to develop and commercialize our current pipeline of additional potential product candidates, our prospects for future growth and our ability to reach or sustain profitability may be limited or never achieved.

A key element of our long-term strategy is to develop, obtain regulatory approval for and commercialize our portfolio of potential product candidates in addition to Twirla. To do so, we plan to utilize our proprietary transdermal delivery technology, Skinfusion®, to develop additional potential product candidates. We may not be successful in our efforts to develop our portfolio of additional potential product candidates, and any potential 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 potential product candidates, 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 shorter, lighter periods, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP and AG200-ER are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial approved use. In July 2016, we began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower dose combination EE/LNG patch (SmP) in the fourth week of the woman's cycle. We have decided to postpone the trial and will continue to evaluate the timing for initiating dosing of subjects for this Phase 2 clinical trial, which is dependent on financial and other capital resources. Our planned Phase 2 clinical trial of AG200-SP (SmP) is only the initial clinical trial in this program and AG200-SP (SmP) will require additional clinical trials to establish the safety and efficacy of this potential product candidate. The other potential product candidates in our pipeline will require additional product development efforts to optimize patch formulations and dosing. In addition, we will need to conduct additional clinical trials to establish the safety and efficacy of these potential product candidates, which will require additional capital. Substantially all of our resources are currently dedicated to the manufacturing, validation and commercialization of Twirla. We will require additional capital to complete the commercialization plan for Twirla and to advance the development of our other potential product candidates.

Our development programs may initially show promise in identifying potential product leads yet fail to produce potential product candidates for clinical development. In addition, identifying new treatment needs and potential 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 potential 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 potential product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development.

Any clinical development activities, including clinical trials, necessary to obtain and maintain regulatory approvals may not be successfully completed.

Twirla is our first approved product. While we have one approved product, we may not be successful in conducting and managing the clinical activities, including clinical trials, necessary to obtain and maintain regulatory approvals, which might prevent us from successfully designing, implementing, or completing the clinical trials required to support regulatory approval of our potential product candidates and meet our post-marketing study requirements. The application, approval and maintenance process for the FDA and other regulatory agencies are complex and difficult and vary by regulatory agency, and we might not be able to demonstrate that our potential product candidates or Twirla meet the appropriate standards for initial and continued regulatory approval or initiate and continue to commercialize Twirla or our potential product candidates, if approved, in the U.S. or elsewhere, or we might be significantly delayed in doing so. In such circumstances, our business, financial condition, results of operations and prospects and the value of our common stock may be materially adversely affected.

If we experience any of a number of possible unforeseen events in connection with clinical trials related to our potential product candidates, or Twirla, any potential marketing authorization or commercialization of our potential product candidates could be delayed or prevented or we may not be able to meet our post-marketing study requirements for Twirla.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our potential product candidates, may prevent us from meeting our Twirla post-marketing study requirements, or which may adversely impact our commercialization of Twirla including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, or we may be required to modify the Twirla label, or regulators may withdraw Twirla approval or impose other conditions or restrictions, such as REMS;
- the number of patients required for clinical trials of our product and potential 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;
- we may enroll patients at clinical trial sites in countries that are inexperienced with clinical trials in general;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require us to submit additional data, conduct additional studies or amend our investigational new drug application, or IND, or comparable application prior to commencing a clinical trial;
- we may have delays in reaching or may fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our potential product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- regulators may determine that our studies, study design, or data analyses do not meet their regulatory requirements;
- the supply or quality of our potential product candidates, Twirla, or other materials necessary to conduct clinical trials may be insufficient or inadequate; or
- Twirla or our potential product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the trials.

Our costs will increase if we experience delays in testing, completion of post-marketing studies, or, for our potential product candidate marketing authorizations. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

For Twirla, failure to complete post-marketing studies may also result in enforcement actions or removal of the product from the market. Adverse post-marketing study results may also result in withdrawal or limitations on marketing applications, label changes, or other restrictions or requirements, such as REMS or additional study requirements.

For our potential product candidates, we cannot commercialize any potential product candidates in the U.S. without first obtaining FDA approval. Before obtaining regulatory approvals for commercial sale, however, we must demonstrate in, or rely on data from preclinical studies and well controlled clinical trials that the potential product candidate is safe and effective for use in the target indication and that the manufacturing processes, facilities, and controls are adequate. Obtaining marketing approval in the U.S. is a lengthy, expensive and uncertain process, and approval may not be obtained or may be subject to significant restrictions. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential product candidates, allow our competitors to bring products to market before we do, or impair our ability to successfully commercialize our potential product candidates, and so may harm our business, results of operations and financial condition. Delays in regulatory approvals or failure to obtain regulatory approval for a potential product candidate may result from many factors, including:

- Regulatory requests for additional analyses, reports, data, nonclinical and preclinical studies, product design work and testing, and manufacturing development work;
- Regulatory questions regarding interpretation of data or new information regarding the potential product candidate or other products;
- Regulators may not agree with the design of our studies or our statistical analysis, may interpret our data differently than we do, or may find that our study results are not supportive of approval;
- Our studies may reveal unfavorable or inconclusive results, including unfavorable results regarding the potential product candidate's safety or efficacy;
- Regulators may determine that our potential product candidates present an unacceptable health risk or that the product's candidate's risks outweigh any benefits;
- Regulators may not approve our manufacturing facilities or processes following a facility inspection;

- Regulators may determine that our studies were not properly conducted or did not comply with regulatory requirements;
- We and regulators may not come to an agreement on product labeling;
- We may have insufficient funds to pay FDA's significant application user fees;
- We may not be able to use FDA's 505(b)(2) NDA pathway due to changes in FDA's interpretation of the law; and
- We may face patent challenges that may result in stays on FDA's ability to approve our potential product candidates.

Delays or failure to receive regulatory approval for any additional potential product candidates may materially impact our business.

We may be unable to license or acquire suitable additional potential 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 potential 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 potential 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 potential product candidates within our areas of expertise; or
- We may not have sufficient funds to acquire, develop or commercialize additional potential 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 December 31, 2019, we had a total of 15 full-time employees reflecting a resumption of hiring to advance the commercialization of Twirla. We use third-party consultants to assist with our sales and marketing functions. As our commercialization of Twirla advances, we expect to need to expand the size of our employee base for managerial, operational, commercial, sales, marketing, compliance, regulatory, finance and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Twirla and any other future potential 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. Additionally, at times, we have also implemented programs that included cash retention bonuses and/or restricted stock units as incentives to retain employees.

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 employment agreements with our named executive officers which includes Alfred Altomari, our Chairman and Chief Executive Officer. The employment agreements provide 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 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 commercialize Twirla, as well as our potential 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 potential product candidates, if approved.

We face potential risks of product liability as a result of the clinical testing and commercial availability of Twirla and the clinical testing of our other potential product candidates. For example, we may be sued if Twirla or any potential 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 or development of the product or potential 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 potential 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;
- Regulatory authority withdrawal of product approvals or refusal to approve pending applications;
- Loss of revenue;
- The inability to commercialize Twirla or our potential product candidates, if approved;
- A decline in our stock price; and
- Exposure to adverse publicity.

We have obtained limited product liability insurance coverage for Twirla 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 Twirla or of potential 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.

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 Capital Market, impose various requirements on public companies, including requiring the 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. Our testing, and 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 common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Capital 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 potential product candidates and could disrupt our sales.

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

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

Despite the implementation of security measures, our internal computer systems, and those of 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, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. 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 commercialization of Twirla and/or development of our potential product candidates could be delayed.

Our employees, independent contractors, principal investigators, CROs, manufacturers, 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, manufacturers, 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.

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 of 1986, as amended, 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. Our net operating loss carryforwards arising in taxable years ending on or prior to December 31, 2017 will expire between 2019 and 2037 if we have not used them. Net operating loss carryforwards arising in taxable years ending after December 31, 2017 are no longer subject to expiration under the Code.

In addition, it is possible that the transactions relating to our initial public offering or subsequent public offerings, either on a standalone basis or when combined with future transactions, have 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 of the Code. 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

We expect that our stock price may fluctuate significantly.

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 annual report, these factors include:

- Our failure to commercialize Twirla or develop and commercialize additional potential product candidates;
- 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 potential product candidates;
- Changes in laws or regulations applicable to Twirla or any future potential product candidates, including but not limited to clinical trial requirements for approvals, post-approval requirements, and product marketing, advertising, and promotional requirements and limitations;
- 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 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 Capital 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.

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

The 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. 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, 2019, our executive officers, directors, director nominees, holders of 5% or more of our capital stock and their respective affiliates together beneficially owned approximately 17.7% of our outstanding voting stock.

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 public and private offerings. 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 completed public and private offerings. 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 completed public and private offerings. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from our completed public and private offerings in a manner that does not produce income or that loses value.

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 require us to 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 conducts 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 Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial

reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

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;

- 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal offices occupy approximately 8,200 square feet of leased office space in Princeton, New Jersey pursuant to a lease agreement that expires in November 2020. 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

None.

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 was listed on the Nasdaq Global Market under the symbol "AGRX" from May 23, 2014 through January 2, 2019. Beginning on January 3, 2019, our common stock has been listed on the Nasdaq Capital Market under the symbol "AGRX".

	High	Low
Year Ended December 31, 2019		
Fourth Quarter	$2.97	$0.35
Third Quarter	$1.64	$0.95
Second Quarter	$1.56	$1.02
First Quarter	$1.70	$0.66
Year Ended December 31, 2018		
Fourth Quarter	$1.30	$0.33
Third Quarter	$0.92	$0.23
Second Quarter	$3.00	$0.49
First Quarter	$3.92	$2.40

As of February 18, 2020, we had 34 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 February 18, 2020 was $3.94.

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. In addition, our Credit Agreement and Guaranty among us, the gurantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, as a lender and as Administrative Agent for the lenders, contains, and any other loan facilities that we may enter into may contain, restrictions on our ability to pay dividends. Subject to such restrictions, 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.

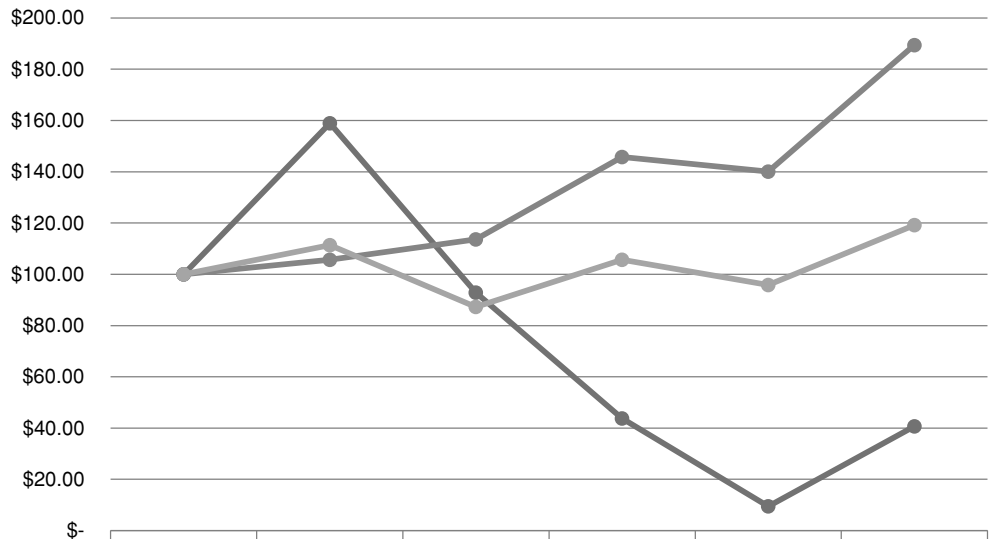
Stock Performance Graph

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, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act of 1933, as amended.

The following graph shows a comparison from December 31, 2014 through December 31, 2019 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 December 31, 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 Cumulative Total Return
December 31, 2019



	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Agile Therapeutics, Inc.	$100.00	$158.96	$92.83	$43.81	$9.45	$40.72
Nasdaq Composite	$100.00	$105.73	$113.66	$145.76	$140.10	$189.45
Nasdaq Biotechnology	$100.00	$111.42	$87.26	$105.64	$95.79	$119.17

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

None.

Issuer Purchases of Equity Securities

None.

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 on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K.

We have derived the statement of operations data for the years ended December 31, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016 and 2015 are derived from our audited financial statements that are not included in this Annual

Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands, except share and per share amounts)				
Statement of Operations Data:					
Operating expenses:					
Research and development	$ 9,858	$ 9,777	$ 14,428	$ 20,929	$ 25,622
General and administrative	9,000	8,739	12,383	8,792	7,467
Restructuring costs	—	1,019	—	—	—
Total operating expenses	18,858	19,535	26,811	29,721	33,089
Loss from operations	(18,858)	(19,535)	(26,811)	(29,721)	(33,089)
Other income (expense)					
Interest income	252	366	282	117	5
Interest expense	—	(1,116)	(1,918)	(2,446)	(2,077)
Change in fair value of warrants	—	29	143	234	(110)
Loss on extinguishment of debt	—	—	—	—	(1,036)
Total other income (expense), net	252	(721)	(1,493)	(2,095)	(3,218)
Loss before benefit from income taxes	(18,606)	(20,256)	(28,304)	(31,816)	(36,307)
Benefit from income taxes	—	477	—	3,075	5,972
Net loss	$ (18,606)	$ (19,779)	$ (28,304)	$ (28,741)	$ (30,335)
Net loss per share (basic and diluted)	$ (0.38)	$ (0.58)	$ (0.91)	$ (1.02)	$ (1.38)
Weighted-average common shares (basic and diluted)	49,432,487	34,315,931	30,940,831	28,273,331	22,017,229

	As of December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$34,479	$ 7,851	$35,952	$48,750	$34,395
Working Capital	31,524	6,240	22,442	40,548	30,151
Total Assets	49,540	22,392	50,595	63,866	50,712
Accounts Payable	1,819	875	2,784	2,050	2,387
Loan payable, current	—	—	10,607	5,104	—
Loan payable, long-term	—	—	—	10,607	13,035
Total stockholders' equity	45,745	20,174	36,323	42,289	29,743

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 healthcare company dedicated to fulfilling the unmet health needs of today's women. Twirla® and our potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Twirla, our first and only approved product, is a once-weekly prescription combination hormonal contraceptive patch. Twirla is designed using our proprietary transdermal patch technology, called Skinfusion®, designed with properties to optimize patch adhesion and patient wearability, which may help support compliance while, for the first time, delivering a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs. We believe there is an unmet market need for a contraceptive patch that is designed to delivers approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient dosage form that may support compliance in a non-invasive fashion.

Twirla was approved for sale in the United States on February 14, 2020 as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. Based on the observed relationship between efficacy and BMI in a Phase 3 clinical trial, Twirla's limitation of use instructs healthcare providers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to <30 kg/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2 because compared to women with a lower BMI, women in this group had reduced effectiveness and may have a higher risk for VTEs.

As part of Twirla's approval, the FDA is requiring us to conduct a long-term prospective, observational post-marketing study comparing the risks for VTE and ATE in new users of Twirla to new users of other CHCs. The FDA's requirement for Twirla is similar to another post-marketing study requirement for a recently approved CHC. The final study report for the Twirla post-marketing study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. We have also agreed to a small post-marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla. The PMC study is similar to residual drug studies requested of patch developers in the FDA's November 2019 draft guidance entitled Transdermal and Topical Delivery Systems—Product Development and Quality Considerations. We are evaluating the design and cost of these post-marketing studies

With the approval of Twirla we now plan to focus on our transition from a clinical development stage company to a commercial company. During 2020, we plan to begin the implementation of our

commercialization plan for Twirla and to manage the growth of our company. Our near term plan for the commercialization of Twirla includes:

Activity	Expected Timing
Initiate coverage and reimbursement activities in the United States from third-party payors.	First Quarter 2020
Initiate hiring of contract sales force	Second Quarter 2020
Complete pre-validation and validation of the commercial manufacturing process consistent with our approved marketing application	Second Half 2020 with first shipment of product in the Fourth Quarter 2020.

Our short-term goal is to establish an initial franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. To that end, our goal is to begin the pre-validation and validation of the commercial manufacturing process in the first half of 2020, manufacture three validation batches of Twirla and complete the process in the second half of 2020. At the same time, we will prepare for the availability of commercial product supply. In the first quarter of 2020, we plan to initiate work with managed care and patient payors to gain market access for Twirla. In the second quarter of 2020, we plan to begin hiring and training an initial sales team, which we estimate to be in the range of 70 to 100 persons. We intend to ship product to wholesalers in fourth quarter of 2020. We also expect to explore the advancement of our existing pipeline and its possible expansion through business development activities.

Our current priorities are as follows:

- Successfully complete the pre-validation and validation process for the commercial manufacturing of Twirla;
- Obtain coverage and reimbursement for Twirla in the United States from third-party payors;
- Implement our commercialization plans for Twirla to ensure a successful launch in the United States, including building a sales and marketing team and implementing a healthcare compliance program;
- Establish a supply chain for Twirla that will support commercialization across the United States at launch;
- Complete the design and protocol of the FDA-required post-marketing long-term observational study comparing risks for VTE and ATE in new users of Twirla to new users of other CHCs;
- Explore the advancement of our existing pipeline and its possible expansion through business development activities.

For more information about the regulatory history of Twirla, please see *Part 1, Item 1, "Business"*

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for 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 $9.9 million, $9.8 million and $14.4 million during the years ended December 31, 2019, 2018 and 2017, respectively. While we anticipate that a portion of our operating expenses will continue to be related to research and development as we complete the pre-validation manufacturing activities related to Twirla, conduct our Phase 4 study, and plan the development of our pipeline, we expect our operating expenses to substantially shift towards commercialization. A

substantial amount of our resources are currently dedicated to completing manufacturing validation and commercializing Twirla.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of December 31, 2019, and 2018, respectively, we had $34.5 million and $7.9 million in cash and cash equivalents.

In January 2019, we entered into a common stock sales agreement or the "2019 ATM Agreement," under which we were authorized to sell up to an aggregate of $10.0 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). We agreed to pay a commission of 3% of the gross proceeds of any common stock sold under this agreement. During the year ended December 31, 2019, we issued and sold a total of 1,801,528 shares of common stock under the 2019 ATM Agreement resulting in net proceeds of approximately $2.5 million. We terminated the 2019 ATM Agreement on July 31, 2019.

In March 2019, we completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the private placement, net of offering costs, were approximately $7.8 million.

In August 2019, we completed a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $12.7 million.

In November 2019, we entered into a second ATM Agreement, or the "Second 2019 ATM Agreement," under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $20.0 million from time to time. We paid a commission of 3% of the gross proceeds from the sales of our common stock under the Second 2019 ATM Agreement. In the year ended December 31, 2019, we issued and sold 10,440,908 shares of common stock under the second 2019 ATM Agreement, representing all the capacity of Second ATM Agreement, resulting in net proceeds of approximately $19.3 million.

In February 2020, we entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, or Perceptive, for a senior secured term loan facility of up to $35 million, which we refer to as the Perceptive Credit Agreement. A first tranche of $5 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA. Another $15 million tranche will be available upon the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date.

We have not generated any revenue and have never been profitable for any year. Our net loss was $18.6 million, $19.8 million and $28.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we commercialize Twirla. This includes completing the qualification and validation of our commercial manufacturing process, initiating pre-launch commercial activities, commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs. We will require additional capital to fund these activities and to advance the development of our other potential product candidates.

Going Concern

As of December 31, 2019, we had cash and cash equivalents of $34.5 million. Additionally, in February 2020, we received $20.0 million in gross proceeds under the Perceptive Credit Agreement. We believe that our cash and cash equivalents as of December 31, 2019, along with the proceeds of the Perceptive Credit Agreement we have received to date, will be sufficient to meet our projected operating requirements through the end of 2020. We will require additional capital to fund our

operating needs beyond 2020, which we expect primarily will consist of commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. Our ability to continue operations beyond 2020 will depend on our ability to obtain additional funding, as to which no assurances can be given. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern for twelve months from the date of filing of this Annual Report on Form 10-K. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

We continue to analyze strategic and financing alternatives, potential asset sales as well as mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders will experience dilution. 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 obtain funds when needed or on acceptable terms, we then may be unable to complete the commercialization of Twirla and may also be required to further cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional capital, reduce expenditures and/or execute on our business plan and successfully launch Twirla. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We do not own any manufacturing facilities and rely on our contract manufacturer, Corium, for all aspects of the manufacturing of Twirla. We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the validation of Corium's commercial manufacturing line for Twirla and be capable of supplying projected commercial quantities of Twirla. In September 2019, we re-started manufacturing development at Corium. We are currently working with Corium to complete manufacturing development, process improvements, and pre-validation work. Our goal is to manufacture three validation batches of Twirla and complete the validation of the commercial manufacturing process in the second half of 2020. We expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs and compliance functions.

We have incurred and will continue to incur additional costs associated with operating as a public company. Accordingly, we will need additional capital to support our continuing operations and other potential product candidates in our pipeline in addition to the commercial activities required for the pre-launch and launch of Twirla. 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 capital may not be available to us on acceptable terms, or at all. Our failure to raise additional 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 successfully commercialize 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 potential 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, including the supply of our potential product candidates;
- costs associated with research, development and regulatory activities; and
- costs associated with equipment scale-up required for commercial manufacturing.

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 and to date, our research and development expenses have been related primarily to the development of Twirla. 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.

For the years ended December 31, 2019, 2018 and 2017, our research and development expenses were approximately $9.9 million, $9.8 million and $14.4 million, respectively. The following table summarizes our research and development expenses by functional area.

	Year ended December 31,		
	2019	2018	2017
	(In thousands)		
Clinical development	$1,781	$1,318	$ 2,386
Regulatory	2,990	562	1,348
Personnel related	1,669	2,162	2,440
Manufacturing—commercialization	2,876	4,306	5,917
Manufacturing	20	155	1,153
Stock-based compensation	522	1,274	1,184
Total research and development expenses	$9,858	$9,777	$14,428

It is difficult to determine with any certainty the exact duration and completion costs of any of our future clinical trials of Twirla or our current and future potential product candidates we may advance. It is also difficult to determine if, when or to what extent we will generate revenue from the commercialization and sale of Twirla our potential product candidates that obtain regulatory approval.

The duration, costs and timing of clinical trials and development of our other potential product candidates in addition to conducting required post-marketing studies for Twirla will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, obtaining additional capital, 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. Substantially all of our resources are currently dedicated to commercializing Twirla. We will require additional capital to fund our operating needs beyond 2020, which we expect primarily will consist of commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and administrative functions including payroll taxes and health insurance, 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, 2019, 2018 and 2017, our general and administrative expenses totaled approximately $9.0 million, $8.7 million and $12.4 million, respectively. In January 2018, following our receipt of the 2017 CRL, we significantly scaled back our preparations for the commercialization of Twirla, including commercial pre-launch activities, pending our ability to address

the 2017 CRL and receive approval of Twirla. With the recent approval of Twirla, we intend to commercialize Twirla in the United States through a contract sales force. We anticipate that our general and administrative expenses will increase in the future with the commercialization of Twirla. These increases will likely include increased selling and marketing costs, including payroll and operating costs, related to the commercial launch of Twirla, 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.

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;
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies; and
- fees paid to a third-party manufacturer in connection with the development of our commercial manufacturing process.

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. As of December 31, 2019, we did not have any ongoing clinical trials.

Warrant Liability

We account for warrants to purchase common stock in accordance with Accounting Standards Codification, or ASC, 480, *Distinguishing Liabilities from Equity*. ASC 480 requires that a financial instrument, other than an 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 classified as a liability. We measure the fair value of our warrant liability using the Black-Scholes option-pricing model with changes in fair value recognized as increases or reductions to other income (expense) in the statement of operations.

In connection with the completion of our 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. Prior to January 1, 2019, warrants with non-standard anti-dilution provisions (referred to as down round protection) were classified as liabilities and re-measured each reporting period. On January 1, 2019, we adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception,* which indicates that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. We used a modified retrospective approach to adoption, which does not restate our financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $0.2 million with a corresponding adjustment to additional paid-in capital. Warrants to purchase 62,505 shares of common stock at $6.00 per share expired on December 14, 2019, and none of these warrants were outstanding as of December 31, 2019.

The warrants issued in connection with our debt financing completed in February 2015 are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. As of December 31, 2019, there were outstanding 180,274 warrants to purchase common stock at $5.89 per share related to this debt financing. These warrants expire on February 24, 2020.

As part of the February 2020 Perceptive Credit Agreement, we issued Perceptive warrants to purchase 1,400,000 shares of Agile common stock. The per share exercise price for 700,000 shares is $3.74, which is equal to the 5-day volume weighted average exercise price ("5 Day VWAP") as of the trading day immediately prior to closing. The per share exercise price for the remaining 700,000 shares of our common stock is $4.67, which is 1.25 times the 5 Day VWAP.

Stock-Based Compensation

We account for stock-based compensation under ASC 718, *Accounting for Stock Based Compensation*, 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.

We also award restricted stock units ("RSUs") to employees and our board of directors (the "Board"). RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. We expense the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. Cost associated with performance-based restricted stock units with a performance condition which affects the vesting is recognized only if the performance condition is probable of being satisfied.

Comparison of Years Ended December 31, 2019 and 2018

	Year ended December 31,		
	2019	2018	Change
		(In thousands)	
Operating expenses:			
Research and development	$ 9,858	$ 9,777	$ 81
General and administrative	9,000	8,739	261
Restructuring costs	—	1,019	(1,019)
Total operating expenses	18,858	19,535	(677)
Other income (expense)			
Interest income	252	366	(114)
Interest expense	—	(1,116)	1,116
Change in fair value of warrants	—	29	(29)
Total other income (expense), net	252	(721)	973
Loss before benefit from income taxes	(18,606)	(20,256)	1,650
Benefit from income taxes	—	477	(477)
Net loss	$(18,606)	$(19,779)	$ 1,173

Research and development expenses. Research and development expenses increased by $0.1 million, or 0.8%, from $9.8 million for the year ended December 31, 2018 to $9.9 million for the year ended December 31, 2019. This overall increase in research and development expenses was primarily due to the following:

- an increase in regulatory expense of $2.4 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This increase is primarily related to consulting fees incurred in connection with the resubmission of our NDA for Twirla as well as costs associated with the preparation for and attendance at the FDA advisory committee meeting;
- an increase in clinical development expenses of $0.5 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This increase primarily relates to the

costs associated with the comparative wear study of Twirla and Xulane which was initiated and completed during the first quarter of 2019;

- a decrease in manufacturing commercialization expenses of $1.5 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This decrease from 2019 to 2018 reflects reduced activity associated with the scale-up and on-going qualification of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL. Costs related to the qualification, validation and manufacture of Twirla were recorded as research and development expenses until we received approval for the Twirla NDA;
- a decrease in stock compensation expense of $0.8 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants; and
- a decrease in personnel-related expenses of $0.5 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts.

General and administrative expenses. General and administrative expenses increased by $0.3 million, or 3.0%, from $8.7 million for the year ended December 31, 2018 to $9.0 million for the year ended December 31, 2019. This overall increase in general and administrative expenses was primarily due to the following:

- an increase in professional fee expense of $0.8 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This increase primarily relates to the use of financial consultants and recruiting and search fees;
- an increase in advertising and promotion costs of $0.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase relates to additional promotional activities as we prepared for the commercialization of Twirla;
- an increase in insurance costs of $0.2 million for the year ended December 31, 2019 compared to the year ended December 31, 2018; and
- a decrease in stock compensation expense of $1.1 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants.

Restructuring costs. In June 2018, we announced a reduction in our workforce, which resulted in the termination of several employees primarily from our commercial and clinical teams, representing approximately thirty percent of our employees. This workforce reduction, along with other reductions in planned operating expenses was designed to preserve cash while we pursued formal dispute resolution with the FDA for Twirla and as we determine the regulatory path forward for the resubmission of our NDA for Twirla. In addition, in June 2018, we also announced that we had adopted a retention plan to provide (i) cash retention payments to be made to all remaining employees in order to induce such employees to remain employed by us through December 31, 2018 and (ii) stock option grants to all remaining employees in order to induce such employees to remain employed by us through December 31, 2019. Restructuring costs of $1.0 million for the year ended December 31, 2018 represent $0.4 million of severance-related costs and $0.6 million of costs related to the accrual of the retention bonus.

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

Interest expense. Interest expense was primarily attributable to our term loan with Hercules for the year ended December 31, 2018. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Hercules, the amortization of the deferred financing costs associated with the term loan and the accrual of the final payment due to Hercules. We had no interest expense for the year ended December 31, 2019 as the Hercules loan was paid in full in 2018.

Change in fair value of warrants. Prior to our adoption of Accounting Standards Update, or ASU 2017-1, on January 1, 2019 (See Note 2 to the financial statements), certain of our warrants to purchase shares of our common stock were recorded at fair value and were subject to re-measurement at each balance sheet date. These liabilities are re-measured at each balance sheet date with the corresponding charge to earnings recorded within change in fair value of warrant liability. The fair value of the common stock warrants 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, 2018, we reported income of $29 thousand related to the decrease in the fair value of the warrants.

Benefit from income taxes. For the years ended December 31, 2019 and December 31, 2018, we received $0.0 million and $0.5 million, respectively, from the sale of New Jersey state Net Operating Loss Carryovers, or NOLs, as part of the Technology and Business Tax Certificate Program, or the Program. The Program enables approved biotechnology companies to sell their unused NOLs and unused Research and Development Tax Credits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation administer the Program. We have reached the maximum lifetime benefit of $15.0 million under the Program and are no longer eligible to participate in the Program.

Comparison of Years Ended December 31, 2018 and 2017

	Year ended December 31,		
	2018	2017	Change
		(In thousands)	
Operating expenses:			
Research and development	$ 9,777	$ 14,428	$(4,651)
General and administrative	8,739	12,383	(3,644)
Restructuring costs	1,019	—	1,019
Total operating expenses	19,535	26,811	(7,276)
Other income (expense)			
Interest income	366	282	84
Interest expense	(1,116)	(1,918)	802
Change in fair value of warrants	29	143	(114)
Total other income (expense), net	(721)	(1,493)	772
Loss before benefit from income taxes	(20,256)	(28,304)	8,048
Benefit from income taxes	477	—	477
Net loss	$(19,779)	$(28,304)	$ 8,525

Research and development expenses. Research and development expenses decreased by $4.6 million, or 32%, from $14.4 million for the year ended December 31, 2017 to $9.8 million for the year ended December 31, 2018. This overall decrease in research and development expenses was primarily due to the following:

- a decrease in manufacturing commercialization expenses of $2.4 million for the year ended December 31, 2018 as compared to the year ended December 31, 2017. This decrease reflects reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL. Costs related to the qualification, validation and manufacture of Twirla were recorded as research and development expenses until we received approval for the Twirla NDA;
- a decrease in clinical development expenses of $1.1 million for the year ended December 31, 2018 as compared to the year ended December 31, 2017. This decrease primarily relates to the completion of the close-out activities associated with our SECURE clinical trial during 2017. There were no external costs related to the SECURE clinical trial incurred during the year ended December 31, 2018; and
- a decrease in regulatory expenses of $0.8 million for the year ended December 31, 2017 as compared to the year ended December 31, 2018. This decrease primarily relates to reduction of regulatory activity during the year ended December 31, 2018 as compared the year ended December 31, 2017. Regulatory expenses for the year ended December 31, 2017 included external costs associated with the preparation of our NDA resubmission and response to the FDA's CRL received by us in February 2013.

General and administrative expenses. General and administrative expenses decreased by 3.7 million, or 29%, from $12.4 million for the year ended December 31, 2017 to $8.7 million for the year ended December 31, 2018. This decrease in general and administrative expense was primarily due to the following:

- a decrease in commercial development expense of $3.2 million for the year ended December 31, 2018 as compared to the year ended December 31, 2017. This decrease relates to the suspension of our pre-commercialization activities such as brand building, advocacy and consulting as a result of the receipt of the 2017 CRL;
- a decrease in professional fees expense of $0.8 million for the year ended December 31, 2018 compared to the year ended December 31, 2017. This decrease is primarily the result of a reduction in the use of consultants and lower legal and patent-related costs; and
- an increase in personnel costs of $0.7 million for the year ended December 31, 2018 compared to the year ended December 31, 2017, which partially offsets the decreases discussed above. This increase relates to the addition of personnel during the second half of 2017 to help prepare for launch of Twirla, if approved.

Restructuring costs. In June 2018, we announced a reduction in our workforce, which resulted in the termination of several employees primarily from our commercial and clinical teams, representing approximately thirty percent of our employees. This workforce reduction, along with other reductions in planned operating expenses was designed to preserve cash while we pursued formal dispute resolution with the FDA for Twirla and as we determine the regulatory path forward for the resubmission of our NDA for Twirla. In addition, in June 2018, we also announced that we had adopted a retention plan to provide (i) cash retention payments to be made to all remaining employees in order to induce such employees to remain employed by us through December 31, 2018 and (ii) stock option grants to all remaining employees in order to induce such employees to remain employed by us through December 31, 2019. Restructuring costs of $1.0 million for the year ended December 31, 2018

represent $0.4 million of severance-related costs and $0.6 million of costs related to the accrual of the retention bonus.

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

Interest expense. Interest expense is primarily attributable to our term loan with Hercules for the years ended December 31, 2018 and 2017. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Hercules, the amortization of the deferred financing costs associated with the term loan and the accrual of the final payment due to Hercules. Interest expense decreased by $0.8 million, or 42% from $1.9 million for the year ended December 31, 2017 to $1.1 million for the year ended December 31, 2018. This decrease is primarily the result of a decrease in the principal outstanding under our term loan with Hercules for the year ended December 31, 2018 as compared to the year ended December 31, 2017. The term loan with Hercules was paid off on December 1, 2018 and accordingly, we expect no interest expense with respect to the Hercules loan in 2019.

Change in fair value of warrants. Certain of our warrants to purchase shares of our 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 to earnings recorded within change in fair value of warrant liability. The fair value of the common stock warrants 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, 2018, we reported income of $29 thousand related to the decrease in the fair value of the warrants as compared to income of $143 thousand for the year ended December 31, 2017.

Benefit from income taxes. For the year ended December 31, 2018, we received $0.5 million from the sale of New Jersey state Net Operating Loss Carryovers, or NOLs, as part of the Technology and Business Tax Certificate Program, or the Program. We did not receive any payments under the Program during the year ended December 31, 2017. The Program enables approved biotechnology companies to sell their unused NOLs and unused Research and Development Tax Credits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation administer the Program. We have reached the maximum lifetime benefit of $15.0 million under the Program and are no longer eligible to participate in the Program.

Net Operating Losses and Tax Carryforwards

As of December 31, 2019, we had approximately $231.5 million of federal and $92.4 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, for federal net operating losses generated prior to 2018, 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, 2019, all of our net operating losses were fully offset by a valuation allowance.

On December 22, 2017, the United States Congress and the Administration approved a bill reforming the US corporate income tax code which reduced our corporate tax rate from 34% to 21%

effective January 1, 2018. The carrying value of our deferred tax assets is also determined by the enacted US corporate income tax rate. Consequently, any changes in the US corporate income tax rate will impact the carrying value of our deferred tax assets. Under the new corporate income tax rate of 21%, deferred income tax assets decreased by $26.5 million with a corresponding decrease to the valuation allowance. There was no net effect of the tax reform enactment on financial statements.

Liquidity and Capital Resources

In January 2019, we entered into the 2019 ATM Agreement under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $10.0 million from time to time. We paid a commission of 3% of the gross proceeds from the sales of our common stock under the 2019 ATM Agreement. In the year ended December 31, 2019, we sold 1,801,528 shares of common stock under the 2019 ATM Agreement, resulting in net proceeds of approximately $2.5 million. We terminated the 2019 ATM Agreement on July 31, 2019.

In March 2019, we completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from our private placement, net of offering costs were approximately $7.8 million.

In August 2019, we completed a public offering of 14,526,315 shares of our common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $12.7 million.

In November 2019, we entered into the second 2019 ATM Agreement under which we were authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $20.0 million from time to time. We paid a commission of 3% of the gross proceeds from the sales of our common stock under the second 2019 ATM Agreement. In the year ended December 31, 2019, we sold 10,440,908 shares of common stock under the second 2019 ATM Agreement, representing all the capacity available, resulting in net proceeds of approximately $19.3 million.

At December 31, 2019, we had cash and cash equivalents totaling $34.5 million. We invest our cash equivalents in short-term 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,		
	2019	2018	2017
		(In thousands)	
Net cash used in operating activities	$(15,689)	$(16,895)	$(24,560)
Net cash used in investing activities	(98)	(318)	(1,313)
Net cash provided by (used in) financing activities	42,415	(10,888)	13,075
Net increase (decrease) in cash and cash equivalents	$ 26,628	$(28,101)	$(12,798)

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 Twirla was being developed. Net cash used in operating activities was $15.7 million for the year ended December 31, 2019 and consisted of a net loss of $18.6 million and an increase in prepaid expenses of $0.2 million, which was offset by non-cash stock-based compensation expense of $1.8 million and depreciation and amortization of $0.2 million as well as an increase in accounts payable, accrued expenses and other liabilities of $1.1 million which reflects increased commercial development and commercial manufacturing expenses related to the initialization of pre-commercialization activities for Twirla. Net cash used in operating activities was $16.9 million for the year ended December 31, 2018 and consisted of a net loss of $19.8 million which

was offset, in part, by non-cash stock-based compensation expense of $3.6 million and non-cash interest expense of $0.3 million as well as a decrease in accounts payable and accrued liabilities of $1.2 million which reflects higher manufacturing commercialization expenses and the accrued loan fee which were both paid in 2018. Net cash used in operating activities was $24.6 million for the year ended December 31, 2017 and consisted of a net loss of $28.3 million which was offset, in part, by non-cash compensation and non-cash interest expense of $4.3 million as well as a decrease in prepaid clinical trial costs of $1.8 million. Cash used in operations in 2018 was offset, in part, by the proceeds received from the sale of New Jersey NOLs.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2019, 2018 and 2017 was $0.1 million, $0.3 million and $1.3 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, 2019 was $42.4 million which primarily represented net proceeds of $7.8 million received from the issuance of 8,426,750 shares of our common stock in a private placement, net proceeds of $12.7 million from the sale of 14,526,315 shares of common stock through a public offering, and net proceeds of approximately $21.8 million from the sale of a total of 12,242,436 shares of our common stock through two at-the-market, or ATM, sales programs. Net cash used in financing activities for the year ended December 31, 2018 was $10.9 million which represented principal payments under the Hercules Loan Agreement which began on February 1, 2017 and were completed on December 1, 2018. Net cash provided by financing activities for the year ended December 31, 2017 was $13.1 million which included net proceeds of $18.5 million received from the sale of 5,333,334 shares of common stock, offset, in part, by principal payments of $5.6 million under the Hercules Loan Agreement, which began on February 1, 2017.

Funding Requirements and Other Liquidity Matters

We believe that our cash and cash equivalents as of December 31, 2019, along with the proceeds of the Perceptive Credit Agreement that we have received to date, will be sufficient to meet our projected operating requirements through 2020. We will require additional capital to fund our operating needs beyond 2020, including, among other items, the commercialization of Twirla, and advancing the development of our other potential product candidates.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- establish a sales and marketing infrastructure to commercialize Twirla in the United States;
- continue the equipment qualification and validation related to Corium's manufacturing facility in preparation for commercial operations;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to 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 may also need to raise additional funds sooner if we choose to accelerate components of our commercial plan or we encounter any unforeseen events that affect our current business plan, or we may choose to raise additional funds to provide us with additional working capital. Adequate additional

funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms or are unable to enter into strategic collaborations, we then may be unable to successfully commercialize Twirla and may also be required to further cut operating costs, forgo future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. Because of the numerous risks and uncertainties associated with such developments, including, among other things, manufacturing scale up, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the commercialization of Twirla. Our future capital requirements will depend on many factors, including:

- the costs of the equipment qualification and validation related to the expansion of Corium's manufacturing facility in preparation for commercial operations;
- the costs of future commercialization activities, including the commercial launch, product sales, marketing, manufacturing and distribution, for Twirla;
- the revenue, if any, received from commercial sales of Twirla;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

Except for the remaining tranche under the Perceptive Credit Agreement, which is contingent upon achieving certain revenue milestones, we do not have any committed external source of funds. Until such time, if ever, as we can generate substantial cash flows from product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

Going Concern

As of December 31, 2019, we had cash and cash equivalents of $34.5 million. Additionally, in February 2020, we entered into the Perceptive Credit Agreement. A first tranche of $5 million was funded on execution of the agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA (see Note 15). We believe that our cash and cash equivalents as of December 31, 2019 along with the proceeds of the Perceptive Credit Agreement we have received to date, will be sufficient to meet our projected operating requirements through the end of 2020. We will require additional capital to fund our operating needs beyond 2020, which we expect primarily will consist of commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. We continue to analyze strategic and financing alternatives, potential asset sales as well as mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. 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 obtain funds when needed or on acceptable terms, we may

be required to curtail our current development programs, cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next 12 months following the date this Annual Report on Form 10-K is filed. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional capital, reduce expenditures and/or execute on our business plan and successfully launch Twirla. The audited financial statements as of December 31, 2019 do not include any adjustments that might result from the outcome of this uncertainty.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2019 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
			(In thousands)		
Operating lease	191	191	—	—	—
Total	$191	$191	$—	$—	$—

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey. In August 2015, we renewed this lease with the new term to expire in November 2020. We are currently seeking new facilities or considering expanding existing facilities as we consider adding employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Shelf Registration Statements

On November 2, 2018, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $100.0 million, which we refer to as the 2018 Shelf Registration Statement. On November 14, 2018, the 2018 Shelf Registration Statement was declared effective by the SEC.

On January 23, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $10.0 million of shares of our common stock. In the year ended December 31, 2019, we sold a total of 1,801,528 shares of our common stock under this ATM program resulting in net proceeds of approximately $2.5 million. We terminated this at-the-market offering program on July 31, 2019.

In August 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $12.7 million.

On November 8, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $20.0 million of shares of our common stock. In the year ended December 31, 2019, we sold a total of 10,440,908 shares of our common stock under this ATM program, representing all the capacity, resulting in net proceeds of approximately $19.3 million.

Recent Accounting Pronouncements

See Note 2 to our financial statements that discusses new accounting pronouncements.

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

Interest Rate 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 $34.5 million and $7.8 million at December 31, 2019 and December 31, 2018, respectively consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows were subject to fluctuations due to changes in interest rates, principally in connection with our loan agreement with Hercules (through November 30, 2018) and interest income on cash balances. We do not believe we are materially exposed to changes in interest rates. We do not currently use interest rate derivative instruments to manage exposure to interest rate changes. Based on average invested cash of $14.8 million for the year ended December 31, 2019, a 1% increase or decrease in interest rates would have increased or decreased interest income by $148,000 for the year ended December 31, 2019.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the year ended December 31, 2019.

Item 8. Financial Statements and Supplementary Data

Agile Therapeutics, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the stockholders and the board of directors of Agile Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Agile Therapeutics, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, statements of changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, requires additional capital to fund its commercialization activities and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.
Iselin, New Jersey
February 20, 2020

Agile Therapeutics, Inc.

Balance Sheets

(in thousands, except par value and share data)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 34,479	$ 7,851
Prepaid expenses	840	607
Total current assets	35,319	8,458
Property and equipment, net	14,044	13,916
Right of use and other assets	177	18
Total assets	$ 49,540	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,819	$ 875
Accrued expenses	1,804	1,343
Lease payable, curent portion	172	—
Total current liabilities	3,795	2,218
Total liabilities	3,795	2,218
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 69,810,305 and 34,377,329 issued and outstanding at December 31, 2019 and 2018, respectively	7	3
Additional paid-in capital	306,108	261,722
Accumulated deficit	(260,370)	(241,551)
Total stockholders' equity	45,745	20,174
Total liabilities and stockholders' equity	$ 49,540	$ 22,392

See accompanying notes.

Agile Therapeutics, Inc.

Statements of Operations

(in thousands, except share and per share data)

	Year ended December 31,		
	2019	**2018**	**2017**
Operating expenses:			
Research and development	$ 9,858	$ 9,777	$ 14,428
General and administrative	9,000	8,739	12,383
Restructuring costs	—	1,019	—
Total operating expenses	18,858	19,535	26,811
Loss from operations	(18,858)	(19,535)	(26,811)
Other income (expense)			
Interest income	252	366	282
Interest expense	—	(1,116)	(1,918)
Change in fair value of warrants	—	29	143
Total other income (expense), net	252	(721)	(1,493)
Loss before benefit from income taxes	(18,606)	(20,256)	(28,304)
Benefit from income taxes	—	477	—
Net loss	$ (18,606)	$ (19,779)	$ (28,304)
Net loss per share (basic and diluted)	$ (0.38)	$ (0.58)	$ (0.91)
Weighted-average common shares (basic and diluted)	49,432,487	34,315,931	30,940,831

See accompanying notes.

Agile Therapeutics, Inc.

Statements of Changes in Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Net Stockholders' Equity
	Number of Shares	Amount			
Balance December 31, 2016	28,759,731	$ 3	$235,754	$(193,468)	$ 42,289
Share-based compensation—stock options and RSUs	—	—	3,651	—	3,651
Vesting of RSUs	16,667	—	—	—	—
Issuance of common stock in public offering, net of expenses	5,333,334	—	18,535	—	18,535
Issuance of common stock upon exercise of options	76,610	—	152	—	152
Net loss	—	—	—	(28,304)	(28,304)
Balance December 31, 2017	34,186,342	$ 3	$258,092	$(221,772)	$ 36,323
Share-based compensation—stock options and RSUs	—	—	3,630	—	3,630
Vesting of RSUs	190,987	—	—	—	—
Net loss	—	—	—	(19,779)	(19,779)
Balance December 31, 2018	34,377,329	$ 3	$261,722	$(241,551)	$ 20,174
Adjustment to derivitive liabilities upon adoption of ASU 2017-11	—	—	213	(213)	—
Share-based compensation— stock options and RSUs	—	—	1,762	—	1,762
Issuance of common stock in private placement, net of expenses	8,426,750	1	7,809	—	7,810
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	12,242,436	1	21,753	—	21,754
Issuance of common stock upon exercise of stock options	92,271		164	—	164
Proceeds from issuance of common stock in public offering, net of expenses	14,526,315	2	12,685	—	12,687
Vesting of RSUs	145,204	—	—	—	—
Net loss	—	—	—	(18,606)	(18,606)
Balance December 31, 2019	69,810,305	$ 7	$306,108	$(260,370)	$ 45,745

See accompanying notes.

Agile Therapeutics, Inc.

Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net loss	$(18,606)	$(19,779)	$(28,304)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	18	23	23
Amortization	145	—	—
Noncash stock based compensation	1,762	3,630	3,651
Noncash interest	—	282	667
Change in fair value of warrants	—	(29)	(143)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(233)	155	2,006
Accounts payable and accrued expenses	1,377	(1,177)	(2,460)
Lease liability	(152)	—	—
Net cash used in operating activities	(15,689)	(16,895)	(24,560)
Cash flows from investing activities:			
Acquisition of property and equipment	(98)	(318)	(1,313)
Net cash used in investing activities	(98)	(318)	(1,313)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of offering costs	42,251	—	18,535
Principal payments of long-term debt	—	(10,888)	(5,612)
Proceeds from exercise of stock options	164	—	152
Net cash provided by (used in) financing activities	42,415	(10,888)	13,075
Net increase (decrease) in cash and cash equivalents	26,628	(28,101)	(12,798)
Cash and cash equivalents, beginning of year	7,851	35,952	48,750
Cash and cash equivalents, end of year	$ 34,479	$ 7,851	$ 35,952
Supplemental disclosure of noncash financing activities			
Supplemental cash flow information			
Interest paid during the year	$ —	$ 1,370	$ 1,295
Cash paid for income taxes	$ —	$ —	$ —
Non-cash transactions			
Property and equipment purchases included in accounts payable	$ 49	$ —	$ 242

See accompanying notes.

Agile Therapeutics, Inc.

Notes to Financial Statements

December 31, 2019

(in thousands, except share and per share data)

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. ("Agile" or the "Company") was incorporated in Delaware on December 22, 1997. Agile is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. The Company's activities since inception have consisted principally of raising capital and performing research and development, including development of the Company's lead product candidate. The Company is headquartered in Princeton, New Jersey.

The Company's sole approved product, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA in February 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. 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, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, competition from larger companies and compliance with the FDA and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of December 31, 2019, the Company had an accumulated deficit of approximately $260 million. The Company expects to continue to incur net losses into the foreseeable future

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 9), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

Going Concern

As of December 31, 2019, the Company had cash and cash equivalents of $34.5 million. Additionally, in February 2020, the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, or the Perceptive Credit Agreement. A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA (see Note 15). The Company believes that its cash and cash equivalents as of December 31, 2019 along with the proceeds of the Perceptive Credit Agreement received by the date of this report will be sufficient to meet its projected operating requirements through the end of 2020. The Company will require additional capital to fund its operating needs beyond 2020, which primarily will include commercializing Twirla, and exploring the advancement of its existing pipeline and its possible expansion through business development activities.

The Company anticipates it will continue to incur net losses for the foreseeable future and the Company's ability to continue operations beyond 2020 will depend on its ability to obtain additional capital, as to which no assurances can be given. There can be no assurance that any financing by the Company can be realized by the Company, or if realized, what the terms of any such financing may be, or that any amount that the Company is able to raise will be adequate. Based upon the foregoing,

1. Organization and Description of Business (Continued)

management has concluded that there is substantial doubt about the Company's ability to continue as a going concern through the 12 months following the date on which this Annual Report on Form 10-K is filed.

The Company continues to analyze various alternatives, including strategic and refinancing alternatives, asset sales and mergers and acquisitions. The Company's future success depends on its ability to raise additional capital and/or implement the various strategic alternatives discussed above. The Company cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current stockholders will experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company then may be unable to complete the commercialization of Twirla, and may also be required to cut operating costs, and forego future development and other opportunities.

The audited financial statements as of December 31, 2019 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional capital, reduce expenditures and/or execute on its business plan and successfully launch Twirla. The audited financial statements as of December 31, 2019 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

2. Summary of Significant Accounting Polices

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. 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 common stock warrants, stock-based compensation, income taxes, and accounting for research and development costs. Actual results could differ from those estimates.

2. Summary of Significant Accounting Polices (Continued)

Risks and Uncertainties

While Twirla has been approved by the FDA, other potential product candidates developed by the Company will require approval from the FDA prior to commercial sales. There can be no assurance that the Company's other product candidates will receive the required approval. If the Company is denied approval or such approval is delayed, or is unable to obtain the necessary financing to complete development and approval, there could be a material adverse impact on the Company's financial condition and results of operations.

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 maintains balances with financial institutions in excess of the Federal Deposit Insurance Corporation limit.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("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).

Other 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, 2019.

2. Summary of Significant Accounting Polices (Continued)

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, 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 reported as a reduction of the related term loan. 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 approximately $0, $133 and $239 for the years ended December 31, 2019, 2018 and 2017, 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 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 an 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 the Black-Scholes option-pricing model with changes in fair value recognized as increases or reductions to other income (expense) 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. Warrants with non-standard anti-dilution provisions (referred to as down round protection) are classified as liabilities and re-measured each reporting period. On

2. Summary of Significant Accounting Polices (Continued)

January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception,* which indicates that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. The Company used a modified retrospective approach to adoption, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to additional paid-in capital. Warrants to purchase 62,505 shares of common stock at $6.00 per share expired on December 14, 2019, and none of these warrants are outstanding as of December 31, 2019.

The warrants issued in connection with the Company's debt financing completed in February 2015 (see Note 8) are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. As of December 31, 2019, there were outstanding 180,274 warrants to purchase common stock at $5.89 per share related to this debt financing. These warrants expire on February 24, 2020.

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 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, 2019 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 model based on key assumptions such as stock price, expected volatility and expected term. The Company

(in thousands, except share and per share data)

2. Summary of Significant Accounting Polices (Continued)

elects to account for forfeitures when they occur. 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.

The Company also awards restricted stock units ("RSUs") to employees and its board of directors. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. Cost associated with performance-based restricted stock units with a performance condition which affects the vesting is recognized only if the performance condition is probable of being satisfied.

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

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, common stock warrants, unvested RSUs 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 for the years ended December 31, 2019, 2018 and 2017, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	Year Ended December 31,		
	2019	2018	2017
Common stock warrants	180,274	242,779	242,779
Unvested restricted stock units	—	147,554	264,361
Common stock options	7,192,357	5,687,901	3,805,305
Total	7,372,631	6,078,234	4,312,445

2. Summary of Significant Accounting Polices (Continued)

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on our consolidated financial statements or disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company adopted ASU No. 2016-02 on January 1, 2019. The Company recorded a lease asset and lease liability of approximately $0.3 million on its balance sheet as of January 1, 2019, with no impact on its statement of operations.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* This ASU eliminates the requirement to consider "down round" features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity's own stock. On January 1, 2019, the Company adopted the provisions of ASU No. 2017-11 using a modified retrospective approach, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to additional paid-in capital. As a result of the adoption of ASU 2017-11, effective January 1, 2019, the Company no longer measures these warrants at fair value.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to change the terms or conditions of a share-based payment award. The amendments in this ASU provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This Update is the final version of Proposed ASU 2016-360—Compensation—Stock Compensation (Topic 718)—Scope of Modification Accounting, which has been deleted. The amendments in this ASU are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The adoption of this ASU did not have a material impact on the Company's financial statements.

(in thousands, except share and per share data)

2. Summary of Significant Accounting Polices (Continued)

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. ASU 2016-13 was adopted by the Company on January 1, 2020 and has no current impact on the Company as we do not have any financial instruments covered by the topic.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying financial statements.

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—Quoted prices in active markets for identical assets and liabilities. The Company's Level 1 assets consist of cash and cash equivalents. The Company has no Level 1 liabilities.
- 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 has no Level 3 assets or liabilities.

The following tables set forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of December 31, 2019 and 2018:

	Level 1	Level 2	Level 3
2019			
Assets:			
Cash equivalents	$34,444	$—	$—
Total assets at fair value	$34,444	$—	$—

(in thousands, except share and per share data)

3. Fair Value Measurements (Continued)

	Level 1	Level 2	Level 3
2018			
Assets:			
Cash equivalents	$7,776	$—	$—
Total assets at fair value	$7,776	$—	$—

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

Beginning balance at December 31, 2016	$ 172
Change in fair value	(143)
Ending balance at December 31, 2017	29
Change in fair value	(29)
Ending balance at December 31, 2018	—
Change in fair value	—
Ending balance at December 31, 2019	$ —

There were no transfers between Level 1, 2 or 3 during 2019 or 2018.

4. Prepaid Expenses

Prepaid expenses consist of the following:

	December 31,	
	2019	2018
Prepaid insurance	$656	$484
Other	184	123
Total prepaid expenses	$840	$607

(in thousands, except share and per share data)

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 Life
	2019	2018	
Office equipment	$ 49	$ 49	3 - 10 years
Computer equipment	179	175	3 years
Manufacturing equipment	14,203	14,061	5 years
	14,431	14,285	
Less: accumulated depreciation	(387)	(369)	
Property and equipment	$14,044	$13,916	

As of December 31, 2019, and 2018, manufacturing equipment includes approximately $14.0 million and $13.9 million, respectively, of equipment which is in the process of being constructed and qualified and is not currently being depreciated.

6. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2019	2018
Employee bonuses	$1,437	$ 621
Accrued retention bonus	—	638
Accrued professional fees and other	367	84
Total accrued liabilities	$1,804	$1,343

7. Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The Company adopted ASU No. 2016-02 on January 1, 2019 for leases that existed on that date. The Company has elected to apply the provisions of ASC 842 modified retrospectively at January 1, 2019 through a cumulative-effect adjustment. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods. The company recorded a lease asset and lease liability of approximately $0.3 million on its balance sheet as of January 1, 2019, with no impact on its statement of operations.

(in thousands, except share and per share data)

7. Leases (Continued)

The Company has no finance leases and one operating lease for office space in Princeton, NJ. Operating lease expense was $193 for the year ended December 31, 2019.

Operating cash flows used for operating leases during the year ended December 31, 2019 were $152. As of December 31, 2019, the weighted-average remaining lease term was 0.92 years and the weighted average discount rate was 21.2%.

Future minimum lease payments under non-cancellable leases as of December 31, 2019 were as follows:

2020	$191
Total	$191
Less: Interest	(19)
Present value of lease liability	$172

8. Loan and Security Agreement

Hercules Capital, Inc.

In February 2015, the Company entered into a loan and security agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules") for a term loan of up to $25.0 million. In August 2016, the Company entered into the First Amendment to Loan and Security Agreement (the "First Amendment") with Hercules which amended certain terms of the Hercules Loan Agreement. In May 2017, the Company entered into the Second Amendment to Loan and Security Agreement (the "Second Amendment") with Hercules which further amended certain terms of the Hercules Loan Agreement. A first tranche of $16.5 million was funded upon execution of the Hercules Loan Agreement, approximately $15.5 million of which was used to repay the Company's previous term loan with Oxford Finance LLC.

The First Amendment extended the Company's option to draw down the second tranche of $8.5 million (the "Second Term Loan Advance") of the term loan facility provided under the Hercules Loan Agreement (the "Term Loan") until March 31, 2017 and made the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The Second Amendment further extended the Company's option to draw the Second Term Loan Advance until January 31, 2018 and continued to make the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. The First Amendment also extended the interest-only payments until January 31, 2017, in connection with the first tranche of $16.5 million (the "First Term Loan Advance" and together with the Second Term Loan Advance, the "Term Loan Advances"). The period during which the additional tranche of $8.5 million may be drawn has expired and therefore the $8.5 million can no longer be drawn by the Company.

The First Amendment provided the Term Loan matured on December 1, 2018. As a result of the First Amendment, and in connection with the extension of the interest-only period from the First Term Loan Advance, Hercules returned to the Company the principal payments paid by the Company in July

8. Loan and Security Agreement (Continued)

and August 2016, which such returned payments once again constituted outstanding Term Loan advances under the Hercules Loan Agreement. In connection with the execution of the First Amendment, the Company paid Hercules a facility fee of $165. The facility fee represented a debt issue cost which was reflected as a reduction to the carrying amount of the loan payable in accordance with ASU 2015-03. Such issue costs were amortized to interest expense over the life of the Term Loan using the effective interest method. As of December 31, 2019, and 2018, the Company had no outstanding borrowings related to the Hercules Loan Agreement.

The Term Loan accrued interest at a rate of the greater of 9.0% or 9.0% plus Prime minus 4.25% and was payable monthly. Principal was due in 23 consecutive monthly installments beginning on February 1, 2017 and ending on December 1, 2018. In addition to the outstanding principal balance, the Company was required to make a final payment of approximately $611 on the maturity date of the Hercules Loan (December 1, 2018). The amount of the end of term final payment was accrued over the loan term as interest expense.

The obligations of the Company under the Hercules Loan Agreement were secured by a perfected first position lien on all of the assets of the Company, excluding intellectual property assets.

In connection with the Hercules 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 which expires on February 24, 2020 and granted Hercules the right to participate in future equity financings in an amount up to $2.0 million while the loan or warrant are outstanding.

The Company allocated the proceeds of $16.5 million in accordance with ASC 470 based on the relative fair values. The relative fair value of the warrants of approximately $1.2 million at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The significant assumptions used in preparing the option pricing model for valuing the Company's warrant issued to Hercules include (i) volatility (75.0%), (ii) risk free interest rate of 1.22% (estimated using treasury bonds with a 4-year life), (iii) strike price ($5.89) for the common stock warrant, (iv) fair value of common stock ($9.82) and (v) expected life (4 years). The discount on the debt was amortized to interest expense over the term of the debt.

Interest expense on the Hercules Loan Agreement including the accretion of the value of the related warrants, accrual of term loan back-end fee and amortization of the deferred financing costs was approximately $0, $1.1 million and $1.9 million, for the years ended December 31, 2019, 2018 and 2017, respectively.

9. Stockholders' Equity

The Company's Certificate of Incorporation, among other things: (i) authorizes 150,000,000 shares of common stock; (ii) 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; (iii) 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; (iv) provides that directors may only be removed with cause

9. Stockholders' Equity (Continued)

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; (v) provides that only the Board, the chairman of the Board or the chief executive officer may call a special meeting of stockholders; and (vi) 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.

Shelf Registration Statements

On June 19, 2015, the Company filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $150.0 million (the "2015 Shelf Registration Statement"). On July 1, 2015, the 2015 Shelf Registration Statement was declared effective by the SEC. The Company completed an offering of common stock in both January 2016 and August 2017 utilizing the 2015 Shelf Registration Statement. The 2015 Shelf Registration Statement expired on June 30, 2018.

On November 2, 2018, the Company filed a universal shelf registration statement with the Securities and Exchange Commission ("SEC") for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $100.0 million (the "2018 Shelf Registration Statement"). On November 14, 2018, the 2018 Shelf Registration Statement was declared effective by the SEC. In the future, the Company may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2018 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

On January 23, 2019, the Company filed a prospectus supplement to its 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $10.0 million of shares of our common stock. In the year ended December 31, 2019, the Company sold a total of 1,801,528 shares of our common stock under this ATM program resulting in net proceeds of approximately $2.5 million. We terminated this at-the-market offering program on July 31, 2019.

In August 2019, the Company filed a prospectus supplement to its 2018 Shelf Registration Statement registering a public offering of 14,526,315 shares of common stock at a price of $0.95 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses, were approximately $12.7 million.

On November 8, 2019, the Company filed a prospectus supplement to its 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $20.0 million of shares of our common stock. In the year ended December 31, 2019, we sold a total of 10,440,908 shares of our common stock under this ATM program resulting in net proceeds of approximately $19.3 million.

9. Stockholders' Equity (Continued)

Private Placement

In March 2019, the Company completed a private placement of 8,426,750 shares of common stock at $0.93 per share. Proceeds from the Company's private placement, net of offering costs were approximately $7.8 million.

2016 Public Offering of Common Stock

In January 2016, the Company completed an underwritten public offering of 5,511,812 shares of its common stock at a public offering price of $6.35 per share. In February 2016, the underwriters of the public offering of common stock exercised in full their option to purchase an additional 826,771 shares of common stock at the public offering price of $6.35 per share, less underwriting discounts and commissions. A total of 6,338,583 shares of common stock were sold in the public offering resulting in total net proceeds of approximately $37.5 million. One of the Company's stockholders, who is also affiliated with a member of the Board, purchased 393,700 shares of common stock for approximately $2.5 million in the public offering.

2017 Public Offering of Common Stock

In August 2017, the Company completed an underwritten public offering of 5,333,334 shares of its common stock at a public offering price of $3.75 per share. Proceeds from this offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million.

10. Equity Incentive Plans

Stock options

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 non-statutory 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 Board 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. In June 2018, the 2014 Plan was amended and restated, and the Amended and Restated 2014 Incentive Compensation is now referred to as the Amended 2014 Plan. As of December 31, 2019, there were 2,170,175 shares available for future grant under the Amended 2014 Plan.

Through December 31, 2019, the Company granted options to certain employees and nonemployees to purchase shares of common stock at exercise prices ranging from $0.58 to $10.75 per share. The Company recorded noncash stock-based compensation expense for the years ended

(in thousands, except share and per share data)

10. Equity Incentive Plans (Continued)

December 31, 2019, 2018 and 2017 based on the fair market value of the options and shares granted at the grant date. Stock-based compensation expense was as follows:

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 522	$1,274	$1,184
General and administrative	1,240	2,356	2,467
Total	$1,762	$3,630	$3,651

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

	2019	2018	2017
Risk-free interest rate	1.74% - 2.61%	2.57%	2.27%
Expective volatility	65.0%	70.0%	73.9%
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 has elected to record forfeitures as they occur.

As of December 31, 2019, the unrecorded deferred stock-based compensation balance related to stock options was approximately $1.9 million and will be recognized over an estimated weighted-average amortization period of 1.4 years. The weighted average grant date fair value of options granted during the year ended December 31, 2019 was $0.59.

(in thousands, except share and per share data)

10. Equity Incentive Plans (Continued)

The following table summarizes the options outstanding, options vested and the options exercisable as of December 31, 2019, 2018 and 2017:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2017	3,805,305	5.74	7.4	
Options granted	2,230,000	1.96		
Options exercised	—	—		
Options cancelled/forfeited	(347,404)	4.19		
Options outstanding at December 31, 2018	5,687,901	4.34	7.4	
Options granted	2,805,600	1.18		
Options exercised	(92,271)	1.78		
Options cancelled/forfeited	(1,208,873)	2.70		
Options outstanding at December 31, 2019	7,192,357	3.42	7.2	$5,256
Options exercisable at December 31, 2019	4,396,577	4.60	6.1	$2,228
Vested and expected to vest at December 31, 2019	7,192,357			$5,256

Intrinsic value in the tables was calculated as the difference between the Company's stock price at December 31, 2019, of $2.50 per share, and the exercise price, multiplied by the number of options.

Restricted Stock Units

During the year ended December 31, 2016, the Company granted 50,000 RSUs to an employee of the Company, 16,666 RSUs vested on the grant date, 16,667 RSUs vested in February 2017 and the remaining 16,667 RSUs vested in February 2018.

During the year ended December 31, 2017, the Company granted a total of 247,694 RSUs to executive officers and directors of the Company. These RSUs vested ratably over a two-year period for the executive officers and on the one-year anniversary of the grant date for the directors.

During the year ended December 31, 2018, the Company granted a total of 108,254 RSUs to executive officers of the Company representing payment for 2017 target bonuses. These RSUs vested on the one-year anniversary of the grant date.

(in thousands, except share and per share data)

10. Equity Incentive Plans (Continued)

The following table shows the Company's restricted stock unit activity during the years ended December 31, 2019, 2018 and 2017:

	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Restricted stock units outstanding at December 31, 2017	264,361	3.16	
Granted	108,254	3.46	
Vested	(225,061)	3.39	$370
Restricted stock units outstanding at December 31, 2018	147,554	3.03	
Vested	(147,554)	3.03	$129
Restricted stock units outstanding at December 31, 2019	—		

Performance Based Restricted Stock Awards

In addition to the RSUs detailed in the table above, during 2017 the Company granted up to 260,000 shares of performance-based restricted stock units ("Performance Units") under the Company's Amended 2014 Incentive Compensation Plan, to executive officers which are primarily contingent upon achievement of performance goals during the performance period beginning on the date of grant and ending on December 31, 2018 as set forth in each officer's performance unit agreement. For awards with a performance condition which affects the vesting of the Performance Units, cost is recognized only if the performance condition is probable of being satisfied. Given the uncertainty of the achievement of the performance goals during the performance period, the Company did not record compensation expense related to these awards for the year ended December 31, 2017. These performance-based restricted stock units expired and were subsequently replaced with new awards in January 2018 (see below).

In January 2018, the Company granted up to 365,000 shares of performance-based restricted stock units ("Performance Units") under the Company's 2014 Incentive Compensation Plan primarily to executive officers, which were largely contingent upon the achievement of performance goals during the performance period beginning on the date of grant and ending on December 31, 2019 as set forth in each individual's Performance Unit agreement. Performance Units granted in January 2018 replaced Performance Units granted in April 2017 which expired. During 2018, 50,000 Performance Units were cancelled and as of December 31, 2018 315,000 Performance Units remained outstanding. The remaining 315,000 Performance Units expired in December 2019 as the performance goals were not achieved, and there are no Performance Units outstanding as of December 31, 2019.

11. Income Taxes

On December 22, 2017, the President of the United States signed into law an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018 (commonly known as "the Tax Cuts and Jobs Act or the "TCJA""), which introduced a comprehensive set of tax reforms. The Tax Cuts and Jobs Act significantly revises U.S. tax law by, among other

11. Income Taxes (Continued)

provisions, lowering the Company's corporate tax rate from 34% to 21% and eliminating or reducing certain income tax deductions.

In December 2017, in accordance with the SEC Staff Accounting Bulletin ("SAB") 118—Income Tax Accounting Implications of the TCJA, the Company recorded tax effects on a provisional basis based on a reasonable estimate. The TCJA did not have a material impact on the Company's financial statements because its deferred temporary differences are fully offset by a valuation allowance and the Company does not have any offshore earnings from which to record the mandatory transition tax. During 2018, the Company completed its analysis under SAB 118 and no additional tax effects due to rate-remeasurement were required to be recorded.

As of December 31, 2019, the Company had available net operating loss carryforwards ("NOLs") of approximately $231.5 million for federal and $92.4 million for state income tax reporting purposes. Under TCJA, the federal NOLs generated in 2019 and 2018, approximately $32.5 million, can be carried forward indefinitely, while the NOLs generated through taxable years ending December 31, 2017, approximately $198.9 million, are available to offset future federal taxable income, if any, through 2037. The Company also has research and development tax credit carryforwards of approximately $6.3 million and $1.6 million for federal and state income tax reporting purposes, respectively, which are available to reduce federal income taxes, if any, through 2039 and state income taxes, if any, through 2034.

The Internal Revenue Code of 1986, as amended (the "Code") provides for a limitation on the annual use of NOLs 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 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 is likely to 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, 2019, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2016 through December 31, 2018 are still subject to examination by major tax jurisdictions. However, the Internal Revenue Service ("IRS") and state tax jurisdictions can audit the NOLs generated in prior years in the years that those NOLs are utilized.

For all years through December 31, 2019, the Company generated research credits 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

(in thousands, except share and per share data)

11. Income Taxes (Continued)

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,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 55,216	$ 51,240
Research credit carryforward	7,609	6,904
Stock options and other	3,225	2,655
Total gross deferred tax assets	66,050	60,799
Valuation allowance for deferred tax assets	(66,050)	(60,799)
Net deferred tax assets	$ —	$ —

The net change in the valuation allowance for the years ended December 31, 2019 and 2018 was an increase of $5.3 million and an increase of $4.8 million, respectively.

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

	December 31,		
	2019	2018	2017
Federal income tax at statutory rate	21.0%	21.0%	34.0%
State income tax benefit, net of federal benefit	7.0%	6.0%	6.0%
Research and development tax credits	4.0%	3.0%	3.0%
Effect of tax rate changes	0.0%	0.0%	−94.0%
Other	−4.0%	−4.0%	−1.0%
Decrease (increase) to valuation allowance	−28.0%	−24.0%	52.0%
Effective income tax rate	0.0%	2.0%	0.0%

Sale of New Jersey Net Operating Losses

2018

The Company has participated in the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program") sponsored by The New Jersey Economic Development Authority. The Program enables approved biotechnology companies with unused NOLs and unused research and development credits to sell these benefits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The Program is administered by The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation. In January 2018, the Company completed the sale of NOLs totaling approximately

(in thousands, except share and per share data)

11. Income Taxes (Continued)

$0.5 million. This amount is a current state tax benefit and is reflected in the statement of operations for the year ended December 31, 2018. The Company has now reached the maximum lifetime benefit of $15.0 million under the Program and will no longer be eligible to participate in the Program.

12. Restructuring Costs

In June 2018, the Company announced a reduction in its workforce, which resulted in the termination of several employees primarily from the Company's commercial and clinical teams, representing approximately thirty percent of its employees. This workforce reduction, along with other reductions in planned operating expenses is designed to preserve cash while the Company pursued formal dispute resolution with the FDA for Twirla and determines a regulatory path forward for the resubmission of the Company's NDA for Twirla.

In June 2018, the Company also announced that it had adopted a retention plan (the "Retention Plan") to provide (i) cash retention payments to all remaining employees in order to induce such employees to remain employed by the Company through December 31, 2018 and (ii) stock option grants to all remaining employees in order to induce such employees to remain employed by the Company through December 31, 2019.

Each employee who participated in the Retention Plan and (i) remained continuously employed by the Company through December 31, 2018 or (ii) was terminated by the Company other than for cause (as defined in an applicable employment agreement, or, if no employment agreement exists, as determined by the Company in good faith) prior to December 31, 2018, was paid a lump-sum cash payment in an amount determined by the compensation committee ("Compensation Committee") of the Company's board of directors at the time of the adoption of the Retention Plan. If an eligible employee terminated service prior to December 31, 2018 for any reason other than termination of employment by the Company without cause, no such cash retention payment was made to the eligible employee. The total amount of the cash portion of the Retention Plan was approximately $0.6 million.

In addition, all remaining employees were granted a stock option to purchase the number of shares of common stock as approved by the Compensation Committee, with a per share exercise price of $0.58, representing the closing price of the Company's common stock as reported by Nasdaq on the date the Retention Plan was approved by the Compensation Committee. Each option vested in four equal 25% installments on the following dates: (i) June 20, 2018, (ii) December 31, 2018, (iii) June 30, 2019 and (iv) December 31, 2019, subject to the employee's continuing service to the Company.

A summary of accrued restructuring costs, included as a component of accrued liabilities on the Company's unaudited December 31, 2019 balance sheet is as follows:

	December 31, 2018	Charges	Payments	December 31, 2019
Accrued retention bonus	638	—	(638)	—
Total	$638	$—	$(638)	$—

13. 2019 Retention Plan

In July 2019, the Company adopted a retention plan (the "2019 Retention Plan") for all employees (with the exception of the Chairman and Chief Executive Officer) in order to induce such employees to remain employed by the Company through at least the PDUFA goal date of November 16, 2019.

Each employee who participates in the 2019 Retention Plan and remains continuously employed by the Company through the Approval shall be paid a lump-sum cash payment in an amount determined for each eligible employee by the Compensation Committee at the time of the adoption of the 2019 Retention Plan. If an eligible employee terminates employment prior to the Approval for any reason, no such retention payment shall be made to the eligible employee. The total amount of the cash portion of the 2019 Retention Plan is approximately $0.3 million. Given that the PDUFA goal date was extended to February 16, 2020 and the ultimate uncertainty of the approval of Twirla, the Company has not recorded compensation expense related to these potential cash awards for the year ended December 31, 2019.

All employees (with the exception of the Chairman and Chief Executive Officer) who were employed by the Company as of July 3, 2019 were also granted a stock option to purchase the number of shares of common stock as approved by the Compensation Committee, with a per share exercise price of $1.48, representing the closing price of the Company's common stock as reported by Nasdaq on the date of grant. Each option will vest in two equal 50% installments on the following dates (i) July 3, 2020 and (ii) December 31, 2020.

In addition, the vesting for the annual stock option grant in January 2019 were amended for all employees holding such options who were employed on July 3, 2019 as follows: 50% of the option will vest on January 29, 2020, 25% on June 30, 2020 and the remaining 25% on December 31, 2020. The change in vesting schedule was approved by the Compensation Committee and did not have a material impact on the Company's statement of operations.

14. Commitments and Contingencies

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. An unfavorable outcome to any legal matter, if material, could have an adverse effect on the Company's operations or its financial position. As of December 31, 2019, the Company has not recorded a provision for any contingent losses.

15. Subsequent Event

In February 2020, the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party, or Perceptive, for a senior secured term loan credit facility of up to $35 million, (the Perceptive Credit Agreement"). A first tranche of $5 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA. Another $15 million tranche will be available to the Company based on the achievement of certain revenue milestones. The facility will be interest only until the third anniversary of the closing date. As part of the Perceptive Credit Agreement, the Company issued Perceptive warrants to purchase 1,400,000 shares of Agile common stock. The per share exercise price

15. Subsequent Event (Continued)

for 700,000 shares is $3.74, which is equal to the 5-day volume weighted average exercise price ("5 Day VWAP") as of the trading day immediately prior to closing. The per share exercise price for the remaining 700,000 shares of Agile common stock is $4.67, which is 1.25 times the 5 Day VWAP.

16. Quarterly Data (Unaudited)

The following tables summarize the quarterly results of operations for each of the quarters in 2019 and 2018. 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 only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein (in thousands, except per share amounts).

	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Total revenue	$ —	$ —	$ —	$ —
Operating expenses	$ 4,707	$ 3,547	$ 4,499	$ 6,105
Net loss	$(4,669)	$(3,484)	$(4,432)	$(6,021)
Basic and diluted net loss per common share	$ (0.13)	$ (0.08)	$ (0.08)	$ (0.10)

	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Total revenue	$ —	$ —	$ —	$ —
Operating expenses	$ 7,046	$ 5,147	$ 3,615	$ 3,727
Net loss	$(6,833)	$(5,344)	$(3,792)	$(3,810)
Basic and diluted net loss per common share	$ (0.20)	$ (0.16)	$ (0.11)	$ (0.11)

The net loss and basic and diluted net loss per share for the quarter ended March 31, 2018 include a tax benefit of $0.5 million from the sale of New Jersey state NOLs. (see Note 11).

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, 2019. 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, 2019, 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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to:

- Provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2019. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework.

Based on its evaluation, our management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to the attestation by our independent registered public accounting firm because as a non-accelerated filer, we are exempt from this requirement.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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.

PART IV

Item 15. Exhibits, 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 immediately preceding the signature page and is incorporated herein by reference.

Exhibit Number	
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	Warrant Agreement between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 4.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 12, 2019.)
4.3	Warrant Agreement between Agile Therapeutics, Inc. and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 4.2 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 12, 2019.)
4.4	Description of Capital Stock
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.)

Exhibit Number	
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+	Form of Performance Unit Issuance Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2018.)
10.6+	Employment Agreement, dated April 12, 2016, by and between the Registrant and Alfred Altomari. (Incorporated by reference, Exhibit 10.2 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on May 9, 2016.)
10.7+	Form of Employment Agreement entered into with non-named executive officers. (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on May 9, 2016.)
10.8*	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.)
10.9	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.)
10.10	Third Lease Amendment, dated August 20, 2015, by and between the Registrant and Bunn Farm Associates, LLC. (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on November 9, 2015.)
10.11	Fourth Lease Amendment, dated April 22, 2016, by and between the Registrant and Bunn Farm Associates, LLC and Fifth Lease Amendment dated December 1, 2016, by and between the Registrant and Bunn Farm Associates, LLC. (Incorporated by reference, Exhibit 10.15 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 12, 2018.)
10.12	Common Stock Sales Agreement dated November 8, 2019 by and between the Registrant and H.C. Wainwright & Co., LLC (Incorporated by reference, Exhibit 1.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on November 8, 2019.)

Exhibit Number	
10.13	Credit Agreement and Guaranty among Agile Therapeutics, Inc., the guarantors from time to time party thereto, the lenders from time to time party thereto and Perceptive Credit Holdings III, LP, dated as of February 10, 2020 (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on February 12, 2020.)
10.14+	Form of Performance Unit Issuance Agreement (Incorporated by reference, Exhibit 10.1 to Company's Current Report on Form 8-K, file number 001-36464, filed on January 26, 2018.)
10.15+	Agile Therapeutics, Inc. Amended and Restated 2014 Incentive Compensation Plan (Incorporated by reference, Appendix A to Registrant's Proxy Statement pursuant to Section 14(a) of the Securities Exchange Act of 1934, file number 001-36464, filed on April 25, 2018.)
10.16	Clinical Research Agreement, dated October 26, 2018, by and between the Registrant and TKL Research, Inc. (Incorporated by reference, Exhibit 10.24 to Company's Annual Report on Form 10-K, file number 001-36464, filed on March 12, 2019.)
10.17	Employment Agreement dated July 16, 2019 by and between the Registrant and Dennis P. Reilly. (Incorporated by reference, Exhibit 10.1 to Company's Quarterly Report on Form 10-Q, file number 001-36464, filed on October 28, 2019.)
23.1	Consent of Independent Registered Public Accounting Firm.
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 12, 2019.
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 12, 2019.
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 12, 2019 (furnished herewith).
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 12, 2019 (furnished herewith).
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Statements of Cash Flows, and (v) the Notes to 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.

Item 16. Form 10-K Summary

None.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 20, 2020.

AGILE THERAPEUTICS, INC.

By /s/ ALFRED ALTOMARI
Alfred Altomari
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange 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)	February 20, 2020
/s/ DENNIS P. REILLY Dennis P. Reilly	Chief Financial Officer (Principal Financial and Accounting Officer)	February 20, 2020
/s/ SETH H.Z. FISCHER Seth H.Z. Fischer	Director	February 20, 2020
/s/ JOHN HUBBARD John Hubbard, Ph.D.	Director	February 20, 2020
/s/ ABHIJEET LELE Abhijeet Lele	Director	February 20, 2020
/s/ WILLIAM T. MCKEE William T. McKee	Director	February 20, 2020
/s/ AJIT S. SHETTY Ajit S. Shetty, Ph.D.	Director	February 20, 2020
/s/ JAMES TURSI James Tursi, M.D.	Director	February 20, 2020

Board of Directors

Alfred Altomari
Chairman and Chief Executive Officer
Agile Therapeutics, Inc.

Seth H.Z. Fischer[(1)(3)]
Strategic Consultant

John Hubbard, Ph.D., FCP[(2)(4)]
Strategic Advisor
Genstar Capital

Abhijeet Lele[(2)(3)]
Lead Independent Director, Agile Therapeutics, Inc.
Managing Director of
Temasek International (USA) LLC

William T. McKee[(1)(2)]
Chief Executive Officer
MBJC Associates, LLC

Ajit S. Shetty, Ph.D.[(3)(4)]
Corporate Vice President
Enterprise Supply Chain
Johnson & Johnson, retired

James P. Tursi, M.D.[(1)(4)]
Executive Vice President,
Head of Research and Development and
Chief Medical Officer
Antares Pharma, Inc.

Standing Committees of the Board of Directors
(1) Compensation Committee
(2) Audit Committee
(3) Nominating and Corporate Governance Committee
(4) Science and Technology Committee

Officers

Alfred Altomari
Chairman and Chief Executive Officer

Dennis P. Reilly
Senior Vice President and Chief Financial Officer

Geoffrey P. Gilmore
Senior Vice President, General
Counsel & Corporate Secretary

Robert G. Conway
Senior Vice President, Chief
Supply Chain Officer

Corporate Headquarters
Agile Therapeutics, Inc.
101 Poor Farm Road
Princeton, New Jersey 08540
Phone: (609) 683-1880
Fax: (609) 683-1855
Website: http://www.agiletherapeutics.com

Transfer Agent and Registrar
Broadridge Corporate Issuer Solutions
P.O. Box 1342
Brentwood, New York 11717

Counsel
Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, New Jersey 08540-6241

Independent Registered Public Accounting Firm
Ernst & Young LLP
99 Wood Avenue South
Iselin, New Jersey 08830

Number of Holders of Common Stock
As of April 20, 2020, there are 34 stockholders of record of Common Stock.

Dividends
The Company has not paid any cash dividends on its Common Stock since its inception and does not anticipate paying any such cash dividends in the foreseeable future.

Market for Common Stock
Nasdaq Capital Market
Symbol: AGRX

SEC Form 10-K and Stockholders' Inquiries
A copy of the Company's Annual Report to the Securities and Exchange Commission on Form 10-K is available without charge. Requests for Form 10-K or other stockholder inquiries should be directed in writing to:

Investor Relations
Agile Therapeutics, Inc.
101 Poor Farm Road
Princeton, New Jersey 08540

Annual Meeting
The Annual Meeting of Stockholders will take place on Thursday, June 9, 2020 at 9:00 a.m. via the internet at www.virtualshareholdermeeting.com/AGRX2020.