AGILE THERAPEUTICS INC
Form 10-Q
May 07, 2018
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 10-Q

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

**For the quarterly period ended March 31, 2018**

**OR**

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

**For the transition period from to**

**Commission File Number 001-36464**

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# 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)

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 x No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an 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 o | Accelerated filer x |
| Non-accelerated filer o (Do not check if smaller reporting company) | Smaller reporting company o |
| | Emerging growth company x |

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. x

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

There were 34,248,268 shares of the registrant s common stock, $0.0001 par value, outstanding as of May 4, 2018.

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**Agile Therapeutics, Inc.**

**Quarterly Report on Form 10-Q**

**For The Quarter Ended March 31, 2018**

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**SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS**

This quarterly report on Form 10-Q 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 varia comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-Q and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development, commercialization, and market uptake of Twirla® (AG200-15) and our other 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 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 Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-Q, 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 adequately and timely respond to the deficiencies in the second Twirla complete response letter, or 2017 CRL, issued by the U.S. Food and Drug Administration, or FDA, on December 21, 2017;

- the potential that the FDA could require us to conduct additional studies to address the concerns raised in the 2017 CRL;

- our ability to resubmit the Twirla new drug application, or NDA, and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our available cash;

- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our ability to obtain additional funding;

- our ability along with our third-party manufacturer, Corium International, Inc., 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 and to pass an FDA pre-approval inspection;

- the performance and financial condition of third-party manufacturers;

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- the success and timing of our clinical trials;
- our ability to retain key employees;
- regulatory and legislative developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in Part I Item 1A. Risk Factors of this Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Form 10-Q 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.

Twirla® is one of our trademarks used in this Form 10-Q. This Form 10-Q also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

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**Agile Therapeutics, Inc.**

**Part I Financial Information**

**ITEM 1. Financial Statements**

**Agile Therapeutics, Inc.**

**Balance Sheets**

**(Unaudited)**

**(in thousands, except par value and share data)**

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,344 | $ 35,952 |
| Prepaid expenses | 633 | 762 |
| Total current assets | 28,977 | 36,714 |
| Property and equipment, net | 13,927 | 13,863 |
| Other assets | 18 | 18 |
| **Total assets** | $ 42,922 | $ 50,595 |
| | | |
| **Liabilities and stockholders equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,071 | $ 2,784 |
| Accrued expenses | 1,130 | 852 |
| Loan payable, curent portion | 9,090 | 10,607 |
| Warrant liability | 22 | 29 |
| Total current liabilities | 12,313 | 14,272 |
| | | |
| **Commitments and contingencies (Note 9)** | | |
| | | |
| **Stockholders equity** | | |
| Common stock, $.0001 par value, 150,000,000 shares authorized, 34,248,268 and 34,186,342 issued and outstanding at March 31, 2018 and December 31, 2017, respectively | 3 | 3 |
| Additional paid-in capital | 259,211 | 258,092 |
| Accumulated deficit | (228,605) | (221,772) |
| **Total stockholders equity** | 30,609 | 36,323 |
| **Total liabilities and stockholders equity** | $ 42,922 | $ 50,595 |

*See accompanying notes to unaudited financial statements.*

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**Agile Therapeutics, Inc.**

**Statements of Operations**

**(Unaudited)**

**(in thousands, except par value and share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Operating expenses: | | |
| Research and development | $ 3,960 | $ 4,721 |
| General and administrative | 3,086 | 2,405 |
| Total operating expenses | 7,046 | 7,126 |
| Loss from operations | (7,046) | (7,126) |
| Other income (expense) | | |
| Interest income | 97 | 47 |
| Interest expense | (368) | (546) |
| Change in fair value of warrants | 7 | 109 |
| Total other income (expense), net | (264) | (390) |
| Loss before benefit from income taxes | (7,310) | (7,516) |
| Benefit from income taxes | 477 | |
| Net loss | $ (6,833) | $ (7,516) |
| Net loss per share (basic and diluted) | $ (0.20) | $ (0.26) |
| Weighted-average common shares (basic and diluted) | 34,229,162 | 28,769,361 |

*See accompanying notes to unaudited financial statements.*

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**Agile Therapeutics, Inc.**

**Statements of Cash Flows**

**(Unaudited)**

**(in thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (6,833) | $ (7,516) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 6 | 5 |
| Noncash stock based compensation | 1,119 | 835 |
| Noncash interest | 139 | 186 |
| Change in fair value of warrants | (7) | (109) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 129 | 243 |
| Accounts payable and accrued expenses | (269) | 348 |
| Net cash used in operating activities | (5,716) | (6,008) |
| | | |
| **Cash flows from investing activities:** | | |
| Acquisition of property and equipment | (276) | (5) |
| Net cash used in investing activities | (276) | (5) |
| | | |
| **Cash flows from financing activities:** | | |
| Principal payments of loan payable | (1,616) | (993) |
| Net cash used in financing activities | (1,616) | (993) |
| | | |
| Net decrease in cash and cash equivalents | (7,608) | (7,006) |
| Cash and cash equivalents, beginning of period | 35,952 | 48,750 |
| Cash and cash equivalents, end of period | $ 28,344 | $ 41,744 |
| | | |
| **Supplemental disclosure of noncash financing activities** | | |
| **Supplemental cash flow information** | | |
| Interest paid | $ 239 | $ 368 |
| Cash paid for income taxes | $ | $ |

*See accompanying notes to unaudited financial statements.*

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(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 forward-thinking 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. The Company is headquartered in Princeton, New Jersey.

The Company s lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. Substantially all of the Company s resources are currently dedicated to developing and seeking regulatory approval for Twirla. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, the difficulties inherent in the development of commercially usable products, the potential need to obtain additional capital necessary to fund the development of its products, and competition from larger companies. The Company has incurred losses each year since inception. As of March 31, 2018, the Company had an accumulated deficit of approximately $228.6 million.

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 7), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding. The Company expects to continue to incur net losses into the foreseeable future.

*Going Concern*

On December 21, 2017, the Company received a complete response letter (the 2017 CRL ) from the FDA citing deficiencies related to the manufacturing process for Twirla and raising questions on the in vivo adhesion properties of Twirla and their potential relationship to the Company s phase 3 clinical trial results. The Company s ability to commercialize Twirla, and the timing of Twirla commercialization, is dependent on FDA s review of the Company s response to the 2017 CRL and its NDA for Twirla, and other items such as timely and successful completion of the validation of equipment for commercial manufacturing, ultimate FDA approval, and additional capital. In January 2018, following the Company s receipt of the 2017 CRL, the Company significantly scaled back its preparations for commercialization of Twirla, including commercial pre-launch and manufacturing validation activities, pending its ability to address the 2017 CRL and receive approval of Twirla. The Company s current business plan assumes resubmission of its NDA for Twirla in the second quarter of 2018, a six-month FDA review of its NDA resubmission, and resumption of both pre-launch commercial activities and pre-validation and validation of the Company s

manufacturing process after Twirla approval, if the FDA approves Twirla. The Company has met with the FDA in a Type A meeting to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. The Company will be better able to determine the timeline for resubmission of the Twirla NDA after receipt of the final meeting minutes from the FDA. The Company will require additional capital to fund operating needs beyond 2018, including among other items, the resumption and completion of our commercialization plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates. The Company cannot assure you that the FDA will approve Twirla, that the FDA s timeline for review will be within six months, or that the Company along with Corium, its third-party manufacturer, will be able to complete validation of the Company s commercial manufacturing successfully and in a timely manner.

The Company s ability to continue operations after December 31, 2018 will depend on its ability to obtain additional funding, 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, there is substantial doubt about the Company s ability to continue as a going concern.

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**1. Organization and Description of Business (Continued)**

As of March 31, 2018, the Company had cash and cash equivalents of $28.3 million. 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 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 may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail its current development programs, cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The unaudited financial statements as of March 31, 2018 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 equity and/or debt financing and reduce expenditures. The accompanying financial statements as of March 31, 2018 do not include any adjustments that might result from the outcome of this uncertainty.

**Basis of Presentation**

The accompanying unaudited interim financial statements have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ) for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC ) for reporting on Form 10-Q. Accordingly, certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company s annual report on Form 10-K for the year ended December 31, 2017 filed with the SEC.

In the opinion of management, the unaudited interim financial statements reflects all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods have been made. The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the operating results for the full fiscal year or any future period.

**2. Summary of Significant Accounting Policies**

The Company s complete listing of significant accounting policies is described in Note 2 to the Company s audited financial statements as of December 31, 2017 included in its annual report on Form 10-K filed with the SEC.

**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.

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

**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.

**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. As of March 31, 2018, there were outstanding 62,505 warrants to purchase common stock at $6.00 per share. These warrants expire on December 14, 2019.

The warrants issued in connection with the Company s debt financing completed in February 2015 (see Note 6) are classified as a component of stockholders equity. The value of such warrants was determined using the Black-Scholes option-pricing model. As of March 31, 2018, 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.

**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 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.

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

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

**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 three months ended March 31, 2018 and 2017, respectively, because to do so would be anti-dilutive (in common equivalent shares):

| | March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Common stock warrants | 242,779 | 242,779 |
| Unvested restricted stock units | 285,948 | 156,667 |
| Common stock options | 4,875,305 | 3,736,720 |
| Total | 5,404,032 | 4,136,166 |

**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.

On January 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers*. Since the Company has not recognized any revenue to date, the adoption of ASC 606 did not have any impact on the Company s financial

statements.

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 will be evaluating the impact of the pending adoption of the new standard on the Company s financial statements.

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. ASU 2017-11 is effective for annual periods beginning after December 31, 2018. Early

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2017-11 on its financial statements.

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.

**3. Fair Value Measurements**

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

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

use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 Quotes prices in active markets for identical assets and liabilities. The Company s Level 1 assets 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. The Company s Level 3 liabilities consist of the warrant liability.

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

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**3. Fair Value Measurements (Continued)**

The following table sets forth the Company s financial instruments measured at fair value by level within the fair value hierarchy as of March 31, 2018 and December 31, 2017.

| | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| **March 31, 2018** | | | |
| Assets: | | | |
| Cash and cash equivalents | $ 27,711 | $ | $ |
| Total assets at fair value | $ 27,711 | $ | $ |
| | | | |
| Liabilities: | | | |
| Common stock warrants | $ | $ | $ 22 |
| Total liabilities at fair value | $ | $ | $ 22 |

| | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| **December 31, 2017** | | | |
| Assets: | | | |
| Cash and cash equivalents | $ 35,870 | $ | $ |
| Total assets at fair value | $ 35,870 | $ | $ |
| | | | |
| Liabilities: | | | |
| Common stock warrants | $ | $ | $ 29 |
| Total liabilities at fair value | $ | $ | $ 29 |

The significant assumptions used in preparing the option pricing model for valuing the Company s warrants as of March 31, 2018 include (i) volatility (70.0%), (ii) risk free interest rate of 2.27% (estimated using treasury bonds with a 1.75 year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($2.57) and (v) expected life (1.75 years).

The significant assumptions used in preparing the option pricing model for valuing the Company s warrants as of December 31, 2017 include (i) volatility (70.0%), (ii) risk free interest rate of 1.89% (estimated using treasury bonds with a 2-year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($2.69) and (v) expected life (2 years).

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

| | | |
|---|---|---|
| Beginning balance at December 31, 2015 | $ | 406 |
| Change in fair value | | (234) |
| Ending balance at December 31, 2016 | | 172 |
| Change in fair value | | (143) |
| Ending balance at December 31, 2017 | | 29 |
| Change in fair value | | (7) |
| Ending balance at March 31, 2018 | $ | 22 |

There were no transfers between Level 1, 2 or 3 during 2018 or 2017. If the Company s estimates regarding the fair value of its warrants are inaccurate, a future adjustment to these estimated fair values may be required. Additionally, these estimated fair values could change significantly.

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**4. Prepaid Expenses**

Prepaid expenses consist of the following:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Prepaid clinical trial expense | $ 205 | $ 205 |
| Prepaid insurance | 253 | 388 |
| Other | 175 | 169 |
| Total prepaid expenses | $ 633 | $ 762 |

**5. Accrued Liabilities**

Accrued liabilities consist of the following:

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Employee bonuses | $ 375 | $ 215 |
| Accrued interest payable | 491 | 451 |
| Accrued professional fees and other | 264 | 186 |
| Total accrued liabilities | $ 1,130 | $ 852 |

**6. Loan and Security Agreements**

*Oxford Finance LLC*

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

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

In connection with the Oxford Loan, the Company issued Oxford warrants to purchase 62,505 shares of common stock at an exercise price of $6.00 per share. These warrants expire on December 14, 2019.

In February 2015, the Company terminated and repaid all amounts outstanding under the Oxford Loan and recorded a loss on the extinguishment of the Oxford Loan (see further discussion below).

*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 existing term loan with Oxford.

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**Agile Therapeutics, Inc.**

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**March 31, 2018**

**(in thousands, except share and per share data)**

**6. Loan and Security Agreements (Continued)**

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 Company is currently in discussions with Hercules to extend the period during which the additional tranche of $8.5 million may be drawn. The Company can make no assurances that its discussions will ultimately be successful and, if such discussions result in an extension of the periods in which the Company may draw the additional tranche of $8.5 million, the Company could incur additional fees to Hercules.

The First Amendment provides the Term Loan will mature 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 and August 2016, which such returned payments will once again constitute 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 represents a debt issue cost which is being reflected as a reduction to the carrying amount of loan payable in accordance with ASU 2015-03. Such issue costs are being amortized to interest expense over the life of the Term Loan using the effective interest method. As of March 31, 2018 and December 31, 2017, the Company had outstanding borrowings of $9.3 million and $10.9 million, respectively, related to the Hercules Loan Agreement which is recorded on the balance sheet in loan payable, current portion.

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

The Company may prepay all, but not less than all, of the Term Loan subject to a prepayment premium of 1.0% of the outstanding principal. The obligations of the Company under the Hercules Loan Agreement are 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 and 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 is being amortized to interest expense over the term of the debt.

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

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**(in thousands, except share and per share data)**

**6. Loan and Security Agreements (Continued)**

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 $368 and $546, for the three months ended March 31, 2018 and 2017, respectively.

**7. Stockholders Equity**

*Shelf Registration Statement*

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 offerings of common stock in both January 2016 and August 2017 utilizing the 2015 Shelf Registration Statement (see below). In the future, the Company may also 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 2015 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.

*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.

*Performance Based Restricted Stock Awards*

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 are 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.

*Stock-Based Compensation Expense*

Stock-based compensation expense was allocated as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Research and development | $ 350 | $ 277 |
| General and administrative | 769 | 558 |
| Total | $ 1,119 | $ 835 |

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**Agile Therapeutics, Inc.**

**Notes to Unaudited Financial Statements**

**March 31, 2018**

**(in thousands, except share and per share data)**

**8. Income Taxes**

*Sale of New Jersey Net Operating Losses*

In January 2018, the Company received net proceeds of approximately $0.5 million in non-dilutive financing through the State of New Jersey s Technology Business Tax Certificate Transfer Program (the Program ). The Program enables approved biotechnology companies to sell their unused Net Operating Loss Carryovers 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. The Company intends to use the proceeds from the sale for working capital purposes. 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.

**9. 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 March 31, 2018, the Company has not recorded a provision for any contingent losses.

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**ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations**

*The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the SEC ) on March 12, 2018. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part 1, Item 1A, Risk Factors of our Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Dollars in the text and in tabular format are presented in thousands, except per share data, or as otherwise indicated.*

**Overview**

We are a forward-thinking women s healthcare company dedicated to fulfilling the unmet health needs of today s women. Twirla and our other current potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, also known as AG200-15, is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development.

Since our inception in 1997, we have devoted substantial resources to developing Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $14.4 million, $20.9 million and $25.6 million during the years ended December 31, 2017, 2016 and 2015, respectively. We incurred research and development expenses of $4.0 million for the three months ended March 31, 2018. We anticipate that a portion of our operating expenses will continue to be related to research and development as we continue to develop Twirla and advance our pipeline of potential product candidates. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs beyond 2018 including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of March 31, 2018 and December 31, 2017 respectively, we had $28.3 million and $35.9 million in cash and cash equivalents.

In February 2015, we entered into a loan and security agreement with Hercules Capital, Inc. or Hercules, for a term loan of up to $25.0 million, which we refer to as 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 our existing term loan. The Hercules Loan Agreement was amended in August 2016 to, among other things, extend the period during which we could have drawn the additional tranche of $8.5 million to March 31, 2017 and extended the period during which we make interest-only payments until January 31, 2017. The Hercules Loan Agreement was further amended in May 2017 to extend the period during which we could have drawn the additional tranche of $8.5 million to January 31, 2018. We are currently in discussions with Hercules to extend the period during which the additional tranche of $8.5 million may be drawn. We can make no assurances that our discussions will ultimately be successful and, if such discussions result in an extension of the periods in which we may draw the additional tranche of $8.5 million, we could incur additional fees to Hercules. On February 1, 2017, we began making principal payments with respect to the Hercules Loan Agreement. See further discussion in Funding Requirements and Other Liquidity Matters below.

In January 2016, we closed an underwritten public offering of 5,511,812 shares of 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.

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

On December 21, 2017, the U.S. Food and Drug Administration, or FDA, issued a complete response letter, or the 2017 CRL, indicating that our resubmitted New Drug Application, or NDA, for Twirla could not be approved in its present form. The 2017 CRL identifies deficiencies relating to quality control adhesion test methods and specification which are part of the manufacturing process for Twirla. The 2017 CRL also noted that objectionable conditions identified during an inspection for the Twirla NDA of our third-party manufacturer, Corium International Inc., or Corium s, facility must be resolved. Prior to receiving the 2017 CRL, we submitted an amendment to our NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality control adhesion test methods cited in the 2017 CRL. In the 2017 CRL, the FDA acknowledged receipt of the amendment and stated that the amendment was not reviewed prior to the FDA s action. In addition, on November 20, 2017 and December 1, 2017, Corium provided the FDA with responses to each of the observations made during the FDA s facility inspection. We believe that the Corium submissions along with our December 1, 2017 NDA amendment will provide a basis for addressing the 2017 CRL. Under the FDA s regulations, we were entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. At our request, the FDA had a Type A meeting with us to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

In addition, while Corium has provided the FDA with responses to each of the observations made during the FDA s facility inspection, we expect that the FDA will re-inspect our manufacturing partner s facilities during its review of our planned resubmission before approval can be granted. The FDA has the authority to re-inspect SECURE clinical trial sites as part of a review of an NDA as well. The FDA may also determine that our responses to the manufacturing deficiencies in the 2017 CRL and Corium s responses to the manufacturing facility inspection observations are not sufficient or require additional analyses and/or studies and deny approval of the Twirla NDA on this basis as well.

In connection with the receipt of the 2017 CRL, and the delay in the approval timeline for Twirla, our ability to continue operations after December 31, 2018 will depend on our ability to obtain additional funding. 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. Based upon the foregoing there is substantial doubt about our ability to continue as a going concern. See further discussion in Funding Requirements and Other Liquidity Matters in this section.

We have not generated any revenue and have never been profitable for any year. Our net loss was $28.3 million, $28.7 million and $30.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. Our net loss was $6.8 million for the three months ended March 31, 2018. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we seek the approval of our NDA for Twirla, complete the qualification and validation of our commercial manufacturing process, initiate pre-launch commercial activities, commercially launch Twirla, if approved, advance our other potential product candidates and expand our research and development programs. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs beyond 2018 including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates.

We do not own any manufacturing facilities and rely on Corium for all aspects of the manufacturing of Twirla. We will continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the equipment qualification and validation related to the expansion of Corium s manufacturing capabilities in order to be capable of supplying projected commercial quantities of Twirla, if approved. We

continue to plan the process of scaling up the commercial manufacturing capabilities for Twirla with Corium and the associated costs and timelines. We expect the validation and expansion of our commercial manufacturing process to be completed

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after the approval of Twirla. If we obtain regulatory approval for Twirla, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of Twirla, including sales, marketing, distribution, medical affairs and compliance functions, which will require additional capital.

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

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue. In the future, we may generate revenue from product sales, license fees, milestone payments and royalties from the sale of products developed using our intellectual property. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Twirla and any product candidates that we may advance in the future. If we fail to complete the development of Twirla or any other potential 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 product candidates;

- costs associated with research, development and regulatory activities; and

- costs associated with equipment scale-up required for commercial production.

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla. In 2018, we expect our research and development expenses to remain relatively consistent with 2017 expenses. Research and development expenses in 2018 will consist primarily of those costs associated with the continued development and refinement of our commercial manufacturing process, preparation and resubmission of the NDA for Twirla, and responding to information requests expected to be received from the FDA as part of their review of our NDA resubmission. In response to the 2017 CRL, we have

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significantly scaled back equipment qualification and validation of our commercial manufacturing process and resumption and completion of these activities will require additional capital.

To date, our research and development expenses have related primarily to the development of Twirla. We expect research and development expenses in 2018 to focus on preparing the resubmission of our new NDA, and also toward the qualification and validation of our commercial manufacturing process. For the three months ended March 31, 2018 and 2017, our research and development expenses were approximately $4.0 million and $4.7 million, respectively. The following table summarizes our research and development expenses by functional area.

| | Three months ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| Clinical development | $ 244 | $ 1,262 |
| Regulatory | 111 | 519 |
| Personnel related | 707 | 771 |
| Manufacturing - commercialization | 2,194 | 1,680 |
| Manufacturing | 354 | 212 |
| Stock-based compensation | 350 | 277 |
| Total research and development expenses | $ 3,960 | $ 4,721 |

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 other 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 our product candidates that obtain regulatory approval.

Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA. We may, however, never succeed in achieving regulatory approval for Twirla or any of our other potential product candidates or such approval may be delayed. The duration, costs and timing of clinical trials and development of our other potential product candidates in addition to 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 developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs beyond 2018 including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates.

***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

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fees for legal, patent review, consulting and accounting services. General and administrative expenses are expensed as incurred.

For the three months ended March 31, 2018 and 2017, our general and administrative expenses totaled approximately $3.1 million and $2.4 million, respectively. In January 2018, following our receipt of the 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, including commercial pre-launch activities, which had primarily increased over the second-half of 2017 as described below, pending our ability to address the 2017 CRL and receive approval of Twirla. However, if Twirla is approved, we intend to commercialize Twirla in the United States through a direct sales force. We anticipate that our general and administrative expenses will increase in the future with the continued research, development and potential commercialization of Twirla, its planned line extensions, and any of our other potential product candidates, and as we operate as a public company. These increases will likely include increased selling and marketing costs, including payroll and operating costs, related to the commercial launch of Twirla, if approved, legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations. Additionally, if in the future we believe regulatory approval of Twirla or any of our other potential product candidates appears likely, we anticipate that we would begin preparations for commercial operations, which would result in an increase in payroll and other expenses, particularly with respect to the sales and marketing of our product candidates.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

There have been no material changes to our critical accounting policies and estimates from the information discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2018 and 2017***

| | Three months ended March 31, | | |
|---|---|---|---|
| | **2018** | **2017** | **Change** |
| Operating expenses: | | | |
| Research and development | $ 3,960 | $ 4,721 | $ (761) |
| General and administrative | 3,086 | 2,405 | 681 |
| Total operating expenses | 7,046 | 7,126 | (80) |

| | | | |
|---|---|---|---|
| Other income (expense) | | | |
| Interest income | 97 | 47 | 50 |
| Interest expense | (368) | (546) | 178 |
| Change in fair value of warrants | 7 | 109 | (102) |
| Total other income (expense), net | (264) | (390) | 126 |
| | | | |
| Loss before benefit from income taxes | (7,310) | (7,516) | 206 |
| Benefit from income taxes | 477 | | 477 |
| Net loss | $ (6,833) | $ (7,516) | $ 683 |

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***Research and development expenses.*** Research and development expenses decreased by $761, or 16%, from $4.7 million for the three months ended March 31, 2017 to $4.0 million for the three months ended March 31, 2018. This decrease in research and development expenses was primarily due to the following:

- a decrease in clinical development expenses of $1.0 million for the three months ended March 31, 2018 as compared to the three months ended March 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 three months ended March 31, 2018;

- a decrease in regulatory expenses of $408 for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017. This decrease primarily relates to reduction of regulatory activity during the three months ended March 31, 2018 as compared the three months ended March 31, 2017. Regulatory expenses for the three months ended March 31, 2017 included external costs associated with the preparation of our NDA resubmission and response to the 2017 CRL; and

- an increase in manufacturing commercialization expenses of $514 for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017. This increase reflects materials, labor and other costs associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment. During the remainder of 2018, we expect these expenses to increase as we address the 2017 CRL from the FDA and continue to advance our plan related to equipment qualification and validation of our commercial manufacturing process and as we continue to prepare for the commercialization of Twirla. Costs related to the qualification, validation and manufacture of Twirla will be recorded as research and development expenses until we receive approval of our NDA for Twirla.

***General and administrative expenses.*** General and administrative expenses increased by $681, or 28%, from $2.4 million for the three months ended March 31, 2017 to $3.1 million for the three months ended March 31, 2018. This increase in general and administrative expense was primarily due to the following:

- an increase in personnel costs of $0.3 million for the three months ended March 31, 2018 compared to the three months ended March 31, 2017. This increase relates to the addition of personnel during the second half of 2017 to help prepare for launch of Twirla, if approved; and

- an increase in commercial development expense of $0.2 million for the three months ended March 31, 2018 compared to the three months ended March 31, 2017. This increase relates to the initiation of certain pre-commercialization activities such as brand building, advocacy and consulting.

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

***Interest expense.*** Interest expense is primarily attributable to our term loan with Hercules for the three months ended March 31, 2018 and 2017, respectively. 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 $0.2 million, or 33%, from $0.5 million for the three months ended March 31, 2017 to $0.4 million for the three months ended March 31, 2018. This decrease is primarily the result of a decrease in the principal outstanding under our term loan with Hercules for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017.

***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

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of the price of the underlying stock. During the three months ended March 31, 2018, we reported income of $7 thousand related to the decrease in the fair value of the warrants as compared to income of $0.1 million for the three months ended March 31, 2017. The market price of our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrant liability.

***Benefit from income taxes.*** For the three months ended March 31, 2018 and 2017, we received $0.5 million and $0, respectively, from the sale of New Jersey state NOLs as part of the Technology and Business Tax Certificate Program (the Program ). The Program enables approved biotechnology companies to sell their unused Net Operating Loss Carryovers 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 intend to use the proceeds from the sale for working capital purposes. 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.

**Liquidity and Capital Resources**

At March 31, 2018, we had cash and cash equivalents totaling $28.3 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:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash used in operating activities | $ (5,716) | $ (6,008) |
| Net cash used in investing activities | (276) | (5) |
| Net cash used in financing activities | (1,616) | (993) |
| Net decrease in cash and cash equivalents | $ (7,608) | $ (7,006) |

***Operating Activities***

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our primary product candidate, Twirla, was being developed. Net cash used in operating activities was $5.7 million for the three months ended March 31, 2018 and consisted primarily of a net loss of $6.8 million which was offset by non-cash stock-based compensation expense of $1.1 million, non-cash interest expense of $0.1 million and a working capital decrease of $0.1 million. Net cash used in operating activities was $6.0 million for the three months ended March 31, 2017 and consisted primarily of a net loss of $7.5 million which was offset by non-cash stock-based compensation expense of $0.8 million and a working capital increase of $0.6 million. Cash used in operations in 2018 has been offset, in part, by the proceeds received from the sale of New Jersey NOLs. The decreased clinical development expenses were offset by increased commercial development and commercial manufacturing expenses related to the initialization of pre-commercialization activities for

Twirla.

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***Investing Activities***

Net cash used in investing activities for the three months ended March 31, 2018 and 2017 was $0.3 million and $5 thousand, respectively. Cash used in investing activities for these periods primarily represents the acquisition of equipment to be used in the commercialization of Twirla, if approved.

***Financing Activities***

Net cash used in financing activities for the three months ended March 31, 2018 was $1.6 million which primarily represented principal payments under the Hercules Loan Agreement, which began on February 1, 2017. Net cash used in financing activities for the three months ended March 31, 2017 was $1.0 million which represented principal payments under the Hercules Loan Agreement.

***Funding Requirements and Other Liquidity Matters***

The resubmission of our NDA for Twirla was received by the FDA on June 26, 2017 and we received a CRL from the FDA on December 22, 2017. Under the FDA s regulations, we were entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. At our request, the FDA had a Type A meeting with us to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for Twirla;
- establish a sales and marketing infrastructure to commercialize Twirla in the United States, if approved;
- continue the equipment qualification and validation related to the expansion of Corium s manufacturing facility in preparation for potential 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.

In January 2018, in response to the 2017 CRL, we significantly scaled back equipment qualification and validation of our commercial manufacturing process and our other commercial pre-launch activities. Based on these actions and our current business plan, we believe that our cash and cash equivalents as of March 31, 2018 will be sufficient to meet our operating requirements through the end of 2018. Our current business plan assumes resubmission of our NDA for Twirla in the second quarter of 2018, a six-month FDA review of our NDA resubmission, and resumption of both pre-launch commercial activities and pre-validation and validation of our manufacturing process after Twirla approval, if the FDA approves Twirla. We have met with the FDA in a Type A meeting to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We will be better able to determine the timeline for resubmission of the Twirla NDA after receipt of the final meeting minutes from the FDA. We will require additional capital to fund operating needs beyond 2018, including among other items, the completion of our commercialization plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the

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development of our other potential product candidates. We cannot assure you that the FDA will approve Twirla, that the FDA s timeline for review will be within six months, or that we will timely complete the qualification and validation of our commercial manufacturing process. We may also need to raise additional funds prior to the end of 2018 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 prior to the end of 2018 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 capital when needed or on attractive terms and not enter into strategic collaborations, we may be required to curtail our current development programs, 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 the development, including, among other things, manufacturing scale up, FDA review of the NDA for Twirla and commercialization of Twirla, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of Twirla;

- the costs of the equipment qualification and validation related to the expansion of Corium s manufacturing facility in preparation for potential commercial operations;

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

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

- 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.

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*

Pursuant to the receipt of the 2017 CRL, and the delay in the approval timeline for Twirla, our ability to continue operations after December 31, 2018 will depend on our ability to obtain additional funding, as to which no assurances can be given. Based upon the foregoing, there is substantial doubt about our ability to continue as a going concern. 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.

As of March 31, 2018, we had cash and cash equivalents of $28.3 million. We continue to analyze various alternatives, including strategic and refinancing alternatives, asset sales and mergers and acquisitions. Our future success depends on our ability to raise capital and/or implement the various strategic alternatives discussed above. 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 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

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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 unaudited financial statements as of March 31, 2018 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 equity and/or debt financing and reduce expenditures. These unaudited financial statements 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 March 31, 2018 that will affect our future liquidity:

| | Total | Less than 1 year | 1 - 3 years | 3 - 5 years | More than 5 years |
|---|---|---|---|---|---|
| Term loan | $ 10,394 | $ 10,394 | $ | $ | $ |
| Operating lease | 541 | 200 | 341 | | |
| Total | $ 10,935 | $ 10,594 | $ 341 | $ | $ |

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.

**February 2015 Loan and Security Agreement Hercules Capital, Inc.**

The first tranche of the Hercules Loan Agreement was funded in February 2015. In August 2016, we entered into the First Amendment to Loan and Security Agreement, or the First Amendment with Hercules which amends certain terms of the Hercules Loan Agreement.

The First Amendment extended our option to draw down the second tranche of $8.5 million referred to as the Second Term Loan Advance , of the term loan facility provided under the Hercules Loan Agreement, or 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 Hercules Loan Agreement was further amended in May 2017 to extend the period during which we could draw the second tranche of $8.5 million to January 31, 2018 and continues to make the Second Term Loan Advance subject to the consent of Hercules, among other customary conditions. We are currently in discussions with Hercules to extend the period beyond March 31, 2017 during which the additional tranche of $8.5 million may be drawn. We cannot assure you that our discussions will ultimately be successful and, if such discussions result in an extension of the period in which we may draw the additional tranche of $8.5 million, we could incur additional fees payable to Hercules. The First Amendment also extended the interest-only payments until January 31, 2017, in connection with the first tranche of $16.5 million, or the First Term Loan Advance, and together with the Second Term Loan Advance, referred to as the Term Loan Advances.

The First Amendment provides that the Term Loan will mature on December 1, 2018. The First Amendment also provides that as part of the extension of the interest-only period from the First Term Loan Advance, Hercules returned to us the principal payments paid by us in July and August 2016, which such returned payments will once again constitute Term Loan Advances under the Hercules Loan Agreement. In connection with the execution of the First Amendment, we paid Hercules a facility fee of $0.165 million.

The Term Loan accrues interest at a rate of the greater of 9.0% or 9.0% plus Prime minus 4.25% and is payable monthly. Principal is due in 23 consecutive monthly installments beginning on February 1, 2017 and ending on December 1, 2018. In addition, we are required to make a final payment of $0.6 million on the maturity date of the Term Loan, December 1, 2018. The final payment is being accrued and recorded to interest expense over the life of the Term Loan. On February 1, 2017, we began making principal payments with respect to the Term Loan.

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We may prepay all, but not less than all, of the Hercules Loan subject to a prepayment premium of 3.0% of the outstanding principal if prepaid during the first year, 2.0% of the outstanding principal if prepaid during the second year and 1.0% of the outstanding principal if prepaid after the second year. Our obligations under the Hercules Loan are secured by a perfected first position lien on all of our assets, excluding intellectual property assets.

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

We 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 discount on the debt is being amortized to interest expense over the term of the debt.

**Shelf Registration Statement**

On June 19, 2015, 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 $150.0 million, which we refer to as the 2015 Shelf Registration Statement. On July 1, 2015, the 2015 Shelf Registration Statement was declared effective by the SEC. During the first quarter of 2016 and the third quarter of 2017, we completed offerings of common stock utilizing the 2015 Shelf Registration Statement (see below). In the future, we 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 2015 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. The 2015 Shelf Registration Statement will expire on July 1, 2018, and we currently plan to file a replacement universal shelf registration statement with the SEC prior to the expiration of the 2015 Shelf Registration Statement.

**2016 Public Offering of Common Stock**

In January 2016, we closed an underwritten public offering of 5,511,812 shares of common stock registered under the 2015 Shelf Registration Statement 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 our stockholders, who is also affiliated with an individual that was at the time a member of our Board of Directors, 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, we completed an underwritten public offering of 5,333,334 shares of common stock registered under the 2015 Shelf Registration Statement at a public offering price of $3.75 per share. Proceeds from this public offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million.

**Recent Accounting Pronouncements**

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

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**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 3. 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 $28.3 million and $35.9 million at March 31, 2018 and December 31, 2017, 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 are subject to fluctuations due to changes in interest rates, principally in connection with the Hercules Loan Agreement. We do not believe that 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. We estimate that a 1% unfavorable change in interest rates would not have a material effect on interest expense for the year ended December 31, 2018.

*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 three months ended March 31, 2018.

**Item 4. Controls and Procedures.**

***Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

***Changes to Internal Controls Over Financial Reporting***

There has been no change in internal controls over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the company s internal control over financial reporting.

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## Part II: Other Information

### Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

### 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 Quarterly Report on Form 10-Q 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 our Overall Business**

***We are significantly dependent on the success of our product candidate, Twirla, which depends on regulatory approval. The FDA may determine our clinical trials or other data and information regarding safety, efficacy, consistency of manufacture or compliance with FDA manufacturing regulations are insufficient for regulatory approval. Failure to obtain regulatory approval or the delay and additional costs that would be required to obtain regulatory approval could require us to reduce or, even discontinue, operations.***

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced product candidate, Twirla. The approval process in the U.S. is uncertain, can take many years and require the expenditure of substantial resources, and we are unable to predict the timing of when regulatory approval may be received, if ever, in any jurisdiction. We are not currently pursuing any regulatory approvals for Twirla or any other potential product candidate outside the United States.

We filed a Section 505(b)(2) NDA, for approval of Twirla by the FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relied in part on clinical trials that we conducted and in part on the FDA s findings of safety and efficacy from investigations for approved products containing the active ingredients and published scientific literature for which we have not obtained a right of reference. In connection with the original submission of our NDA in April 2012, the FDA indicated in a Complete Response Letter, or the 2013 CRL, which we received in February 2013, that our NDA was not sufficient for approval as originally submitted. After multiple communications with the FDA, we received significant guidance as to what additional clinical development and other activities needed to be completed prior to approval. In accordance with the FDA s advice and comments, we conducted an additional Phase 3 clinical trial, the SECURE clinical trial, which was initiated in 2014 and completed in December 2016. We announced the top-line results for the SECURE clinical trial in January 2017. Based on

the guidance that we received from the FDA in connection with our discussions on clinical trial design, we believed that the results from the SECURE clinical trial would address all of the clinical issues raised in the CRL. In June 2017, we resubmitted our Twirla NDA, which was accepted for review and assigned a PDUFA goal date of December 26, 2017.

On December 21, 2017, the FDA issued a second CRL, or the 2017 CRL, indicating that our resubmitted NDA could not be approved in its present form. The 2017 CRL identifies deficiencies relating to quality control adhesion test methods and specifications which are part of the manufacturing process for Twirla. The 2017 CRL also noted that objectionable conditions identified during a pre-approval inspection, or PAI, of a facility of our third-party manufacturer, Corium International Inc., or Corium, for the Twirla NDA must be resolved. Lastly, the 2017 CRL questions the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results, stating that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time. The FDA stated that it is unclear whether the trial results, including the higher than expected Pearl Index for a combined hormonal contraceptive, the discontinuation rate, and rates of unscheduled bleeding were a

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result of the adhesion properties of the product or other factors. The FDA also suggested, if it is determined that the product adhesion concerns are due to the design or formulation of the drug product, that we may need to design a new transdermal system and conduct another clinical trial with the new transdermal system in a U.S. population. The FDA also identified additional pregnancies in women who had delays in applying patches, which they argued should be added to the Pearl Index calculation.

The 2017 CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and *in vivo* adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The 2017 CRL also recommends that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there was any relationship between the adhesion properties and study efficacy, bleeding and discontinuation results. Finally, the 2017 CRL recommends that we address the implications of delays in patch application for real-world use. The 2017 CRL does not identify any issues relating to the safety of Twirla.

Prior to receiving the 2017 CRL, we submitted an amendment to our NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality control adhesion test methods cited in the 2017 CRL. In the 2017 CRL, the FDA acknowledged receipt of the amendment and stated that the amendment was not reviewed prior to the FDA s action. In addition, on November 20, 2017 and December 1, 2017, Corium provided the FDA with responses addressing each of the observations made during the FDA s facility inspection, which included a PAI for Twirla. Under the FDA s regulations, we were entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. At our request, the FDA had a Type A meeting with us to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

We intend to respond to the 2017 CRL, but there can be no assurance that we will address the outstanding FDA questions in a manner sufficient for approval in the U.S. Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA. We disagree with the FDA s conclusions regarding the in vivo adhesion properties of Twirla, and we intend to discuss these with the FDA at the upcoming meeting. We will also address the FDA s questions regarding implications of delays in patch application for real-world use. However, if we are not able to convince the FDA, then these observations could cast doubt on the feasibility of Twirla for real-world use, which could adversely impact our NDA, and ultimately, approval of Twirla. Even if the FDA agrees with our position regarding the relationship between the *in vivo adhesion* properties of Twirla and the efficacy and safety results from our SECURE clinical trial, the FDA may still determine that the need for a convenient, contraceptive patch and the demonstrated efficacy of Twirla, including the pearl index from our SECURE clinical trial, do not outweigh the potential risks associated with the product, and therefore are not sufficient to support the approval of Twirla.

Moreover, before granting product approval and before we can use them in the commercial manufacture of our products, the FDA must determine that Corium s manufacturing facilities meets certain FDA requirements for product manufacturing. We cannot assure you that Corium will be able to address the objectionable conditions found during the FDA s facility inspection. If Corium is not able to address the objectionable conditions to the FDA s satisfaction and we cannot find an alternative supplier, the FDA will not approve our future Twirla NDA resubmission. Failure to comply with the statutory and regulatory requirements further subjects the manufacturer and product sponsor to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product, among other regulatory actions.

Failure to receive approval or significant additional delay in obtaining an FDA decision on whether to approve our resubmitted NDA for Twirla would have a material adverse effect on our business and results of operations, including possible termination of Twirla development and restructuring of our organization, which could include reducing, or even terminating, our operations. In January 2018, following our receipt of

the 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, which reduced our cash outlay; however, we continue to maintain expenditures relating to completing the development and seeking regulatory approval of Twirla. We will require additional funding to complete the commercial validation of the manufacturing process and

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commercial launch for Twirla. We may not be able to obtain sufficient additional funding or generate sufficient revenue and cash flows to continue our operations at planned levels and be forced to reduce, or even terminate, our operations. Even if Twirla is approved, the labeling approved by the FDA may restrict how and to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for Twirla. See, *Risks Related to Regulatory Approval and Clinical Trials for Our Product Candidates, Risks Related to Our Financial Position and Need for Capital, and Risks Relating to the Commercialization of Our Product Candidates, for additional information*.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.***

Our financial statements as of March 31, 2018 have been prepared under the assumption that we will continue as a going concern for the next twelve months. In our Annual Report on Form 10-K for the year ended December 31, 2017, our independent registered public accounting firm has issued a report that includes an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. As of March 31, 2018, we had cash and cash equivalents of $28.3 million. We believe that our cash and cash equivalents should be sufficient to fund our operating expenses through the end of 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the receipt of the 2017 CRL and the delay in the approval timeline for Twirla and as a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including strategic and refinancing alternatives, asset sales and mergers and acquisitions. Our future success depends on our ability to raise capital and/or implement the various strategic alternatives discussed above. 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, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. 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 or even terminate our operations, which may involve seeking bankruptcy protection.

**Risks Related to the Regulatory Approval and Clinical Trials for Our Product Candidates**

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

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

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate.

In the United States, it is necessary to submit a new drug application, or NDA, to obtain FDA approval. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate s safety and efficacy for each desired indication, although we may partially rely on published scientific literature or the FDA s prior approval of similar products. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA may further inspect our manufacturing facilities to ensure that the facilities can manufacture our product candidates and our products, if and when approved, in compliance with the applicable

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regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission, or resubmission, of an NDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions we might make will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not approved, the FDA may require that we conduct additional clinical or preclinical trials, address issues with our manufacturing process or facilities, or take other actions before it will reconsider our application, which we experienced in the previous submissions of our NDA for Twirla in both 2012 and 2017. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

For instance, we filed an NDA, with the FDA for Twirla in April 2012, which included results from two previously conducted Phase 3 clinical trials for Twirla. In response, the FDA issued the 2013 CRL, which identified certain issues, including a request for additional clinical data, quality information and chemistry, manufacturing and controls information, which needed to be addressed before approval could be granted. We continued to interact with the FDA on its CMC and other questions and continued additional supportive testing in order to respond to the FDA s CMC questions. In addition, we gathered the requested information and conducted an additional Phase 3 clinical trial for Twirla, which we refer to as the SECURE clinical trial. The SECURE clinical trial commenced enrollment during the third quarter of 2014 and was completed in December 2016. In January 2017, we announced top-line results. Based on the results of the SECURE clinical trial and additional information relating to the manufacture of Twirla, we resubmitted our NDA which was received by the FDA on June 26, 2017, acknowledged as a complete response ready for FDA review on July 27, 2017, and assigned a target goal date under the Prescription Drug User Fee Act, or PDUFA, for completion of the FDA s review, or Target PDUFA Goal Date, of December 26, 2017.

Our NDA resubmission in 2017 was intended to be a complete response to the 2013 CRL. Although we met with the FDA in October 2013 to discuss an additional Phase 3 clinical trial as requested in the 2013 CRL and received substantial written comments from the FDA in subsequent interactions, we did not seek and have not obtained agreement with the FDA on a special protocol assessment regarding the completed SECURE clinical trial. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constituted a basis for addressing the clinical deficiencies cited in the 2013 CRL. We also requested feedback on whether the proposed Twirla NDA content would meet the FDA s requirements for submission. In April 2017, we received final meeting minutes from our March 2017 meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear acceptable for resubmission and provided feedback on our proposed approach to the FDA s other questions in the 2013 CRL The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA would be sufficient to obtain regulatory approval of Twirla. Our resubmitted NDA included efficacy and safety data from the SECURE clinical trial, the requested manufacturing information, and a summary response to the 2013 CRL and was intended to address the questions raised in the 2013 CRL.

On December 21, 2017, the FDA issued the 2017 CRL, indicating that our resubmitted NDA could not be approved in its present form. The 2017 CRL identifies deficiencies relating to quality control adhesion test methods and specifications which are part of the manufacturing process for Twirla. The 2017 CRL also noted that objectionable conditions identified during a PAI of the Company s third-party manufacturer, Corium, for the Twirla NDA must be resolved. Lastly, the 2017 CRL questions the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results, concluding that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time. The 2017 CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and *in vivo* adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The 2017 CRL also recommends that the Company assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product. Finally, the 2017 CRL recommends that the Company address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. The 2017

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CRL does not identify any specific issues relating to the safety of Twirla. Prior to receiving the 2017 CRL, we submitted an amendment to our NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality control adhesion test methods cited in the 2017 CRL. In the 2017 CRL, the FDA acknowledged receipt of the amendment and stated that the amendment was not reviewed prior to the FDA s action. In addition, on November 20, 2017 and December 1, 2017, Corium provided the FDA with responses addressing each of the observations made during the FDA s facility inspection, which included a PAI for Twirla. Under the FDA s regulations, we were entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. At our request, the FDA had a Type A meeting with us to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

We intend to respond to the 2017 CRL, but there can be no assurance that we will address the outstanding FDA questions in a manner sufficient for approval in the U.S. Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA.

Moreover, before granting product approval and before we can use them in the commercial manufacture of our products, the FDA must determine that Corium s manufacturing facilities meets certain FDA requirements for product manufacturing. We cannot assure you that Corium will be able to address the objectionable conditions found during the FDA s facility inspection. If Corium is not able to address the objectionable conditions to the FDA s satisfaction and we cannot find an alternative supplier, the FDA will not approve our future Twirla NDA resubmission. Failure to comply with the statutory and regulatory requirements subjects the manufacturer and product sponsor to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product, among other regulatory actions.

In connection with our planned resubmission of the Twirla NDA in response to the 2017 CRL, we cannot predict whether regulators will agree that Corium has adequately remedied the objectionable inspection conditions or that we will be able to find an alternative supplier, or whether regulators will agree with our responses to the cited 2017 CRL deficiencies or our conclusions regarding the results of the SECURE clinical trial or any clinical trials we have conducted to date, including whether our data are reliable and generalizable, demonstrate adequate *in vivo* adhesion properties and/or demonstrate adequate safety and efficacy sufficient for approval. For example, based on the SECURE clinical trial top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. If we were to exclude the top-line data on the obese subpopulation, our Pearl Index for non-obese patients was 3.94 with an upper-bound of the 95% confidence interval of 5.35. The highest Pearl Index for a hormonal contraceptive product approved by the FDA to date was 3.19 and the highest upper-bound of the 95% confidence interval was 5.03. In the combined safety database for our three Agile Phase 3 trials (n>3,000), there were 5 subjects with potentially study drug related deep vein thromboses, or DVTs, or pulmonary embolisms, or PEs, 4 of whom were obese (BMI ³ 30 kg/m(2)). Although ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that the Pearl Index is too high to demonstrate efficacy and an adequate risk/benefit profile for either the overall study population or a subgroup of the study population. Accordingly, the FDA may not approve our Twirla NDA. Alternatively, the FDA may determine that for a specific subgroup of patients, Twirla has lower efficacy and presents a higher risk, necessitating labeling restrictions. For instance, the FDA may require labeling restrictions on the use of Twirla for patients in certain BMI categories. We also may not obtain approval of Twirla based on these data or any other basis, or if approved, may only receive approval with significant labeling restrictions.

In addition, while Corium has provided the FDA with responses to each of the observations made during the FDA s facility inspection, we expect that the FDA will re-inspect its facilities during its review of our planned resubmission before approval can be granted. The FDA has the authority to re-inspect SECURE clinical trial sites as part of a review of an NDA as well. The FDA may also determine that our responses to the deficiencies in the 2017 CRL and Corium s responses to the manufacturing facility inspection objectionable conditions are not sufficient or require product development and additional analyses and/or studies and deny approval of the Twirla NDA on this

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basis as well. The FDA may also find additional objectionable conditions upon re-inspection of the Corium facility. If the FDA does not approve the Corium facility for the manufacture of Twirla, or if Corium is not able to address the objectionable conditions found by the FDA, we may need to find an alternative supplier, which will take time and monetary expenditures, and which we may not be able to do on favorable terms to us or at all.

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

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. Even if our product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies, or REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidates. For example, we believe that Twirla, if approved, will have labeling consistent with all other marketed hormonal contraceptive products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clots, heart attacks, thromboembolism, and stroke, as well as liver tumors, gallbladder disease, and hypertension, and a boxed warning regarding risks of smoking and CHC use, particularly in women over 35 years old who smoke. However, regulatory authorities may require the inclusion of additional statements about adverse events in the labeling, including additional black box warnings or contraindications. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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

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

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will ever obtain regulatory approval. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many factors, including:

- Our inability to obtain sufficient funds required to complete clinical development, manufacturing development or regulatory review processes;

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

- Regulatory requests for additional product design work and testing;

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

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

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

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

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

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

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

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

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

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

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

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

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

- Our inability to adequately address the cited deficiencies in the 2017 CRL;

- Corium s inability to adequately resolve the objectionable conditions observed by the FDA when inspecting the facility or our inability to find an alternative supplier;

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- We may be unable to obtain approval for the manufacturing processes or Corium s facilities with whom we contract for clinical and commercial supplies;

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

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

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

For example, we filed an NDA, with the FDA for Twirla in April 2012, which included results from two previously conducted Phase 3 clinical trials for Twirla. The FDA issued a CRL in February 2013, or the 2013 CRL, which identified certain issues, including a request for additional clinical data, quality information and chemistry, manufacturing and controls information, which needed to be addressed before approval could be granted. We continued to interact with the FDA on its chemistry manufacturing and control, or CMC, and other questions and continued additional supportive testing in order to respond to the FDA s CMC questions. In addition, we gathered the requested information and conducted an additional Phase 3 clinical trial for Twirla, which we refer to as the SECURE clinical trial.

In December 2016, we completed the SECURE clinical trial and announced top-line data in early January 2017. In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constitute a basis for addressing the clinical deficiencies cited in the 2013 CRL. We also requested feedback on whether the proposed Twirla NDA content would meet the FDA s requirements for submission. In April 2017, we received final meeting minutes from our March meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear acceptable for resubmission and provided feedback on our proposed approach to certain of the FDA s other questions in the 2013 CRL. The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA will be sufficient to obtain regulatory approval of Twirla. Our resubmitted NDA was received by the FDA on June 26, 2017 and acknowledged as a complete response ready for FDA review on July 26, 2017, with a Target PDUFA Goal Date of December 26, 2017. The resubmitted NDA included efficacy and safety data from the SECURE clinical trial, the requested manufacturing information, and a summary response to the 2013 CRL and was intended to address the questions raised in the 2013 CRL.

On December 21, 2017, the FDA issued the 2017 CRL, indicating that our resubmitted NDA could not be approved in its present form. The 2017 CRL identifies deficiencies relating to quality control adhesion test methods and specifications which are part of the manufacturing process for Twirla. The 2017 CRL also noted that objectionable conditions identified during an inspection of a facility of Corium, for the Twirla NDA must be resolved. Lastly, the 2017 CRL questions the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results, concluding that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time. The 2017 CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and *in vivo* adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The 2017 CRL also recommends that the Company assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product. Finally, the 2017 CRL recommends that the Company address the implications of clinical trial subject patch compliance

and the withdrawal and dropout rates. The 2017 CRL does not identify any specific issues relating to the safety of Twirla. Prior to receiving the 2017 CRL, we submitted an amendment to our NDA on December 1, 2017 in response to an information request from the FDA on the issues related to the quality control adhesion test methods cited in the 2017 CRL. In the 2017 CRL, the FDA acknowledged receipt of the amendment and stated that the amendment was not reviewed prior to the FDA s action. In addition, on November 20, 2017 and December 1, 2017, Corium provided the FDA with responses to each of the observations made during the FDA s facility inspection. Under the FDA s regulations, we were entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant us a meeting date within 30 days of the meeting request. At our request, the FDA had a Type A meeting with us to discuss the deficiencies in

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the Twirla NDA and the regulatory path for approval of Twirla. We plan to provide an update on the outcome of the Type A meeting after we receive the official meeting minutes from the FDA and we will then be better able to determine when we will resubmit our Twirla NDA.

Consistent with our previous NDA resubmission in 2017, we currently expect that our resubmission of the NDA responding to the 2017 CRL will be categorized as a Type 2 resubmission and receive a review period of six months from the date of resubmission of the NDA.

The FDA s review of our planned NDA resubmission is subject to all the risks described above in addition to, among other things, the FDA s assessment of our specific response to the 2017 CRL and the efficacy and safety of Twirla as demonstrated in the final SECURE clinical trial results. The FDA may not agree that our CRL response addresses the agency s concerns or may find that Corium has not adequately addressed the objectionable conditions observed by the FDA during its inspection of the manufacturing facility. If Corium is not able to adequately address the objectionable conditions observed by the FDA, we may need to find an alternative supplier, which would take time and monetary expenditures, and for which there is no guarantee that we will be able to find an acceptable alternative or form a relationship on favorable terms. The FDA may also find that our clinical trial results, including the SECURE clinical trial, do not demonstrate the safety or efficacy of Twirla. The lengthy and unpredictable approval process, as well as the unpredictability of future clinical trial results, may result in our failure to obtain regulatory approval to market Twirla or any of our other potential product candidates, which would significantly harm our business, results of operations and prospects, and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

***The FDA may disagree with our interpretation of clinical results obtained from the SECURE clinical trial, our results do not guarantee support for regulatory approval of our NDA, and, even if the SECURE clinical trial data are deemed to be positive by the FDA, the FDA may disagree with other aspects of the SECURE clinical trial and decline to approve Twirla for the proposed indication.***

We have reported positive top-line data from the SECURE clinical trial. However, even if we believe that the data from the SECURE clinical trial are positive, the FDA could determine that the data from the SECURE clinical trial were negative or inconclusive or could reach a different conclusion than we did on that same data. For instance, following our resubmission of our NDA, the FDA issued the 2017 CRL and raised questions on the *in vivo* adhesion properties of Twirla and their potential adverse impact on our phase 3 clinical trial results, concluded that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time, and recommended that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product, among other recommendations and deficiencies further described in our Annual Report on Form 10-K, which we filed with the SEC on March 12, 2018. Negative or inconclusive results of a clinical trial or difference of opinion could cause the FDA to decline to approve our application or require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results to the satisfaction of the FDA or that the FDA will agree with our interpretation of the results. Any such determination by the FDA would delay the timing of our commercialization plan for Twirla or prevent its further development, or the further development of our other potential product candidates, and adversely affect our business operations. Additionally, the FDA may provide review commentary at any time during the resubmission and review process which could delay the review timeline, adversely affect the review process, or even prevent the approval of Twirla, any of which would adversely affect our business. We may not be able to appropriately remedy issues that the FDA has raised in the 2017 CRL or may raise in its review of our NDA resubmission responding to the 2017 CRL, and we may not have sufficient time or financial resources to conduct future activities to remediate issues raised by the FDA. Moreover, Corium may not be able to remedy the objectionable conditions found during the FDA s facility inspection and we may not be able to find an alternative supplier.

In March 2017, at our request, we met with the FDA to share preliminary data from the SECURE clinical trial, including key safety data and BMI-related efficacy findings, and to seek FDA input as to whether the SECURE clinical trial results constituted a basis for addressing the clinical deficiencies cited in the 2013 CRL. We also requested feedback on whether the proposed Twirla NDA content would meet the FDA s

requirements for submission. In April 2017, we received final meeting minutes from our March meeting with the FDA. The FDA indicated that based on the preliminary information provided by us, the SECURE clinical trial results appear

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acceptable for resubmission and provided feedback on our proposed approach to certain of the FDA s other questions in the 2013 CRL. The FDA further provided responses to us regarding the presentation of efficacy, safety and clinical pharmacology analyses in the NDA and requested that subgroup analysis of efficacy by body weight be provided. The FDA did not provide us with any feedback on whether the results of the SECURE clinical trial and the contents of the planned, resubmitted NDA would be sufficient to obtain regulatory approval of Twirla. There is no guarantee that the data obtained from the SECURE clinical trial will be supportive of, or guarantee, or result in our successfully obtaining FDA approval of Twirla in a timely fashion and for a commercially viable indication, if at all. For example, when we resubmit our NDA to respond to the 2017 CRL, the FDA could determine that the trial did not meet its objectives, or the FDA could still have concerns regarding the conduct of the SECURE clinical trial, including regarding discontinuance of subjects from the trial. At any future point in time, the FDA could require us to complete further clinical or preclinical trials or take other actions which could delay or preclude approval of the NDA and would require us to obtain significant additional funding. There is no guarantee such funding would be available to us on favorable terms, if at all, nor is there any guarantee that FDA would consider any additional information complete or sufficient to support approval. In connection with its review of the planned Twirla resubmission NDA responding to the 2017 CRL, the FDA may hold an advisory committee meeting to obtain committee input on the safety and efficacy of Twirla. Typically, advisory committees will provide responses to specific questions asked by the FDA, including the committee s view on the approvability of the product candidate under review. Advisory committee decisions are not binding but an adverse decision at the advisory committee may have a negative impact on the regulatory review of Twirla. Additionally, we may choose to engage in the dispute resolution process with the FDA if we do not receive approval, which could extend the timeline for any potential approval.

Further, we plan to resubmit our NDA for Twirla with the clinical data from the SECURE clinical trial and additional information and analyses responding to the 2017 CRL. There is no guarantee that such information, data and analyses will be deemed sufficient by the FDA. While we designed the protocols for the SECURE clinical trial and completed analyses to address the issues raised in the 2013 CRL, and are completing the analyses and other requested items from the 2017 CRL, there is no guarantee that the FDA will deem such steps to be sufficient to address those issues when they are formally reviewed as a part of an NDA resubmission or to demonstrate safety and efficacy to the satisfaction of the FDA. The FDA has significant discretion in the review process, and we cannot predict whether the FDA will agree with our conclusions regarding the results of the SECURE clinical trial, including whether our data are reliable and generalizable. For example, the FDA may disagree with our calculations relating to the number of pregnancies occurring on study, or may view the SECURE clinical trial data, and other information and analyses as insufficient to demonstrate a favorable benefit/risk profile for approval for the proposed indication. In addition, based on top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. If we were to exclude the top-line data on the obese subpopulation, our Pearl Index for non-obese patients was 3.94 with an upper-bound of the 95% confidence interval of 5.35. The highest Pearl Index for a hormonal contraceptive product approved by the FDA to date was 3.19 and the highest upper-bound of the 95% confidence interval was 5.03. In the combined safety database for our three Agile Phase 3 trials (n>3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI ³ 30 kg/m(2)). Although ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that our Pearl Index for either the overall study population or a subgroup of the study population or only the non-obese study population is too high to demonstrate efficacy and an adequate risk/benefit profile, and as such, the FDA could decline to approve Twirla on this or any other basis. Also, the FDA may not agree with our analysis of the relationship between BMI and efficacy for Twirla and the FDA may interpret our overall data differently than we do and may decline to approve Twirla on this or any other basis. Furthermore, in connection with the 2017 CRL, the FDA raised questions on the *in vivo* adhesion properties of Twirla and their potential relationship to our phase 3 clinical trial results, concluded that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time, and recommended that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product. The FDA also recommended we address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates, among other recommendations and deficiencies further described in our Annual Report on Form 10-K filed with the SEC on March 12, 2018.

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Moreover, even if we obtain approval of Twirla, any such approval might significantly limit the approved indications for use, including by limiting the approved label for use by more limited patient populations than we propose, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies, or REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of Twirla. For example, the FDA may deem the higher Pearl Index in the obese subpopulation when combined with safety findings for this subpopulation to warrant a labeling limitation or warning for such subpopulation, which could limit the commercial potential of the product, if approved. Moreover, because we did not conduct any head-to-head studies of Twirla against Ortho Evra, we will not be able to make direct comparative claims regarding the safety, efficacy or pharmacokinetics of Twirla and Ortho Evra or its generic version, Xulane®.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the subject populations and the rates of dropout among clinical trial subjects. Our future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for our product candidates. For example, we received the 2013 CRL from the FDA with respect to an NDA previously filed for Twirla, in which the FDA requested, among other items, additional Phase 3 clinical data to support the application. The SECURE clinical trial was designed in consultation with the FDA and is different than the design of our previous clinical trials of Twirla and it is possible that the FDA could conclude that there was significant variability in the safety and efficacy results of these trials. Additionally, while our SECURE clinical trial was designed and implemented in a manner to address the FDA s comments and guidance, it is possible that the FDA could ultimately conclude that the data are not supportive of approval. Specifically, following our resubmission of our NDA, the FDA issued the 2017 CRL and raised questions on the *in vivo* adhesion properties of Twirla and their potential adverse impact on our phase 3 clinical trial results, concluded that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time, and recommended that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product, among other recommendations and deficiencies further described in our Annual Report on Form 10-K which we filed with the SEC on March 12, 2018. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our clinical trials may not be successful.

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

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

If the results of the clinical trials for our current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of our product candidates will be materially adversely affected. For example, in the 2013 CRL that we received from the FDA in connection with the NDA previously filed for Twirla, one of the FDA s comments was

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that acceptable evidence of efficacy was not demonstrated, as measured by Pearl Index, or PI. Specifically, in our completed Phase 3 trials, the PI was higher than that seen in registration trials for previously approved hormonal contraceptives. Experts seem to agree that inconsistent or incorrect use is a major contributor to the increased PI seen in more recent contraceptive trials. The PI values from clinical trials are also affected by additional factors, including differences in study design, increased sensitivity of early pregnancy tests, weight and body mass index, or BMI, of the study population and user experience. For example, consistent with other recent hormonal contraceptive clinical trials, including Ortho Evra® and Quartette®, and the 2015 meta-analysis conducted by the FDA authors on the effect of obesity on the effectiveness of hormonal contraceptives, a relationship between obesity and efficacy was observed among subjects 35 years of age and under in our SECURE clinical trial. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer-term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier preclinical studies have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. The FDA may interpret the data from the SECURE clinical trial differently than we do and may decline to approve Twirla on this or any other basis.

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

- Clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or implement a clinical hold;

- The number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate. For instance, we experienced a high withdrawal rate in our original Phase 3 clinical trials for Twirla and we experienced slower than anticipated enrollment in our SECURE clinical trial;

- Our third-party contract research organization, or CRO, or study sites may fail to comply with regulatory requirements or the clinical trial protocol or meet their contractual obligations to us in a timely manner, or at all. For instance, investigator compliance with study procedures was an issue that we encountered in our two Phase 3 clinical trials for Twirla completed prior to SECURE;

- Regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;

- We may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CRO;

- We may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;

- We may elect or be required to suspend or terminate clinical trials of our product candidates based on a finding that the subjects are being exposed to health risks, or due to other reasons;

- The cost of clinical trials for our product candidates may be greater than we anticipate;

- The supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- There may be changes in government regulations or administrative actions;

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

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

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

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

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

In December 2016, we completed our SECURE clinical trial for Twirla and, as we have previously announced, we expect to conduct additional clinical trials in the future for our other potential product candidates subject to available funding. Subject enrollment for our future clinical trials, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

- Size and nature of the subject population;

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

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

- Eligibility and exclusion criteria for the trial;

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

- Competing clinical trials;

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

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

- Inability to obtain or maintain subject informed consents;

- Risk that enrolled subjects will drop out before completion;

- Subject s relationship with her partner; and

- Other events that may occur and are beyond our control.

Furthermore, we plan to rely on a CRO and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we may have agreements governing their committed activities, we have limited influence over their actual performance. Additionally, the CRO and clinical trial sites may have business, regulatory, personnel or other issues that keep us from satisfactorily completing our clinical trials. Any delays or unanticipated problems during clinical trials, such as additional monitoring of clinical trial sites, slower than anticipated enrollment in our clinical trials or subjects dropping out of or being excluded from participation in our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval

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process and harm our business. For example, we experienced a slower than expected rate of enrollment for our SECURE clinical trial of Twirla, which we began enrolling in the fourth quarter of 2014, and, as a result, we completed the clinical trial in December 2016.

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

If we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. For example, the FDA issued the 2013 CRL in response to our original NDA for Twirla requesting, among other items, an additional Phase 3 clinical study, which has delayed our ability to obtain regulatory approval for that product candidate. Furthermore, the FDA issued the 2017 CRL in response to the NDA we resubmitted in 2017 and raised questions on the *in vivo* adhesion properties of Twirla and their potential relationship to our phase 3 clinical trial results, concluded that we have not established that Twirla has the adhesion properties requisite for safe and effective use at this time, and recommended that we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product candidate. The FDA also recommended we address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates, among other recommendations and deficiencies further described in our Annual Report on Form 10-K, which we filed with the SEC on March 12, 2018. We may also experience delays due to changes in regulatory requirements and guidance, which may require protocol amendments or the conduct of additional studies. These amendments and additional studies may require regulatory or IRB approval. The approval and conduct of these studies may delay, limit or preclude regulatory approval for our product candidates. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

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

Unforeseen adverse effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. In the combined safety population of our Phase 3 trials completed prior to the SECURE clinical trial, there were a total of 22 serious adverse events, or SAEs, of which 16 occurred in the Twirla cohort, which had approximately 2.3 times as many subjects as the oral contraceptive comparator cohort. Three of the 16 SAEs in the Twirla cohort (0.2% of the overall Twirla safety population) were considered to be possibly related to Twirla, and included one drug overdose with Benadryl, one case of uncontrollable nausea and vomiting and one instance of DVT. In addition to the SAEs described above, some subjects taking Twirla experienced non-serious adverse events, such as nausea, headache, application site irritation and breast tenderness. Subjects receiving the oral contraceptive comparator also experienced non-serious adverse events such as nausea, headache and breast tenderness, though at different rates. In the SECURE clinical trial, SAEs were observed in approximately 2.0% of the SECURE clinical trial population, and 0.6% of subjects had SAEs that were considered potentially study drug related, including DVT, PE, gallbladder disease, ectopic pregnancy, and depression. In the combined safety database for the three Agile Phase 3 trials (n >3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI >30kg/m(2)).

Any undesirable adverse effects that may be caused by our product candidates could interrupt, delay or halt clinical trials and could result in more restrictive labeling or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For instance, the FDA may determine that for specific subgroups of patients, Twirla has lower efficacy and presents a higher risk. Accordingly, the FDA may not approve our Twirla NDA or may require labeling restrictions. By example, the FDA may require labeling restrictions on the use of Twirla for patients in certain BMI categories. Adverse effects in any clinical trial could also impact subject recruitment or the ability or willingness of enrolled subjects to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

- Regulatory authorities may withdraw their approval of the product;

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

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

- The FDA may require the establishment or modification of a REMS or a comparable foreign authority may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such adverse effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on us;

- We may be required to conduct additional trials;

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

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- We may be subject to litigation or product liability claims, fines, injunctions or criminal penalties;
- Regulatory authorities may impose additional restrictions on marketing and distribution of the product; and
- Our reputation may suffer.

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

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

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA s previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials or measurements to support any deviation from the previously approved product and to support the reliance on the applicable published literature or referenced product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product s label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. We have submitted an NDA for Twirla under Section 505(b)(2) and as such the NDA relied, in part, on the FDA s previous findings of safety and efficacy from investigations for approved products containing ethinyl estradiol, or EE, and levonorgestrel, or LNG, and published scientific literature for which we have not received a right of reference. We also plan to rely on the 505(b)(2) pathway for our other product candidates. We received the 2013 CRL in response to our initial Section 505(b)(2) NDA for Twirla, as well as our NDA resubmission. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for Twirla, the FDA may require us to perform additional clinical trials or measurements to support approval over and above the clinical trials that we have already completed. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our product candidates, including Twirla.

***Our product candidates may be considered to be combination products by FDA. If they are, the requirements that we are required to comply with will be more complex.***

Our product candidates may be considered by the FDA to be drug-device combination products. While our product candidates, as a whole, will be subject to the drug approval process, we and any of our contractors will be required to comply with the FDA regulatory requirements related to both drugs and devices. For instance, drug-device combination products must comply with both the drug cGMPs and device QSRs, which may be done using a streamlined approach. Additionally, drug-device combination products will be subject to additional reporting requirements. The development of drug-device combination products will also be more complex because the sponsor of the product application will need to demonstrate the combined safety and efficacy of the drug and device components. These requirements will require additional effort and monetary expenditure to ensure that our and our partners products and product candidates are in compliance.

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**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. 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 $28.3 million, $28.7 million and $30.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. Our net loss was $6.8 million for the three months ended March 31, 2018. As of March 31