AGILE THERAPEUTICS INC
Form 10-Q
November 02, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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 September 30, 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

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions 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	Smaller reporting company x
	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 34,377,329 shares of the registrant s common stock, $0.0001 par value, outstanding as of November 1, 2018.

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Agile Therapeutics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 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:

- the fact that our existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory approval process for Twirla and the potential that we may be unable to raise additional financing on terms acceptable to us, or at all;

- the potential that we are required to reformulate Twirla and, if required, our ability to develop or fund a reformulation that will address the FDA s concerns, including showing bioequivalence, if necessary;

- the potential that we are unable to successfully complete the wear study of Twirla and Xulane® suggested by the U.S. Food and Drug Administration, or FDA;

- our ability to adequately and timely respond to the deficiencies in our second Twirla complete response letter, or 2017 CRL, including the Pearl Index that the FDA noted is substantially higher than previously approved combined hormonal contraceptives;

- the potential that the FDA could require us to conduct additional studies to address the concerns raised in the 2017 CRL, which could include an additional Phase 3 trial, in the event we are required to reformulate Twirla;

- the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, in addition to the planned correspondence regarding the design of the suggested wear study;

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- 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;

- the potential that other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, including a determination by an Advisory Committee that Twirla should not be approved;

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

- 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;

- 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.

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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)

		September 30, 2018		December 31, 2017
Assets				
Current assets:				
Cash and cash equivalents	$	16,926	$	35,952
Prepaid expenses		731		762
Total current assets		17,657		36,714
Property and equipment, net		13,921		13,863
Other assets		18		18
Total assets	$	31,596	$	50,595
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	$	488	$	2,784
Accrued expenses		2,022		852
Loan payable, current portion		5,905		10,607
Warrant liability				29
Total current liabilities		8,415		14,272
Commitments and contingencies (Note 10)				
Stockholders equity				
Common stock, $.0001 par value, 150,000,000 shares authorized, 34,377,329 and 34,186,342 issued and outstanding at September 30, 2018 and December 31, 2017, respectively		3		3
Additional paid-in capital		260,919		258,092
Accumulated deficit		(237,741)		(221,772)
Total stockholders equity		23,181		36,323
Total liabilities and stockholders equity	$	31,596	$	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 September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Operating expenses:				
Research and development	$ 1,549	$ 3,175	$ 7,921	$ 11,694
General and administrative	1,767	3,526	7,173	9,130
Restructuring costs	299		715	
Total operating expenses	3,615	6,701	15,809	20,824
Loss from operations	(3,615)	(6,701)	(15,809)	(20,824)
Other income (expense)				
Interest income	91	78	289	187
Interest expense	(268)	(459)	(955)	(1,509)
Change in fair value of warrants		(20)	29	82
Total other income (expense), net	(177)	(401)	(637)	(1,240)
Loss before benefit from income taxes	(3,792)	(7,102)	(16,446)	(22,064)
Benefit from income taxes			477	
Net loss	$ (3,792)	$ (7,102)	$ (15,969)	$ (22,064)
Net loss per share (basic and diluted)	$ (0.11)	$ (0.22)	$ (0.47)	$ (0.74)
Weighted-average common shares (basic and diluted)	34,377,329	31,937,628	34,295,240	29,847,972

See accompanying notes to unaudited financial statements.

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Agile Therapeutics, Inc.

Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30, 2018	2017
Cash flows from operating activities:		
Net loss	$ (15,969)	$ (22,064)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	18	16
Stock based compensation expense	2,827	2,727
Noncash interest	367	520
Change in fair value of warrants	(29)	(82)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	31	1,606
Accounts payable and accrued expenses	(1,004)	(1,473)
Net cash used in operating activities	(13,759)	(18,750)
Cash flows from investing activities:		
Acquisition of property and equipment	(318)	(771)
Net cash used in investing activities	(318)	(771)
Cash flows from financing activities:		
Principal payments of loan payable	(4,949)	(4,035)
Proceeds from the issuance of common stock, net		18,536
Proceeds from exercise of stock options		76
Net cash (used in) provided by financing activities	(4,949)	14,577
Net decrease in cash and cash equivalents	(19,026)	(4,944)
Cash and cash equivalents, beginning of period	35,952	48,750
Cash and cash equivalents, end of period	$ 16,926	$ 43,806
Supplemental disclosure of noncash financing activities		
Supplemental cash flow information		
Interest paid	$ 625	$ 1,023
Cash paid for income taxes	$	$

See accompanying notes to unaudited financial statements.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 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, including development of the Company s lead product candidate. 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 in the United States. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, competition from larger companies and compliance with U.S. Food and Drug Administration (the FDA) and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of September 30, 2018, the Company had an accumulated deficit of approximately $237.7 million. The Company expects to continue to incur net losses into the foreseeable future.

The Company has financed its operations to date primarily through the issuance and sale of its common stock in both public and private offerings (see Note 7), private placements of its convertible preferred stock, venture loans, and non-dilutive grant funding.

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 the 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 the company s ability to secure 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. In April 2018, the Company 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, and the Company announced the content of the official minutes from the meeting in May 2018.

In June 2018, the Company announced it had submitted a formal dispute resolution request (FDRR) with the FDA for Twirla. The dispute pertained to the determination from the FDA s reviewing Division of Bone, Reproductive and Urologic Products (DBRUP) that concerns surrounding the in vivo adhesion properties of Twirla prevent the approval and could not be addressed through the Company s proposed patient compliance programs. The initial FDRR was submitted in June 2018 and was reviewed by the Office of Drug Evaluation III (ODE III), which denied the Company s appeal on July 20, 2018. The Company then escalated its appeal to the Office of New Drugs (OND).

In October 2018, the OND formally denied the Company s appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that the Company reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2018

(in thousands, except share and per share data)

by DBRUP. Specifically, OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that the Company first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. The wear study suggested by OND to address adhesion provides a path forward for resubmission of the NDA for Twirla, but is not intended to address efficacy. Rather, if the wear study is successful, Twirla s safety and efficacy, including the Pearl Index that FDA noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after the Company resubmits the NDA for Twirla. This is an issue that the FDA plans to bring to Advisory Committee after the adhesion issue has been resolved. The Company has submitted a request for a Type A meeting and plans to discuss the specifics of the proposed wear study with the FDA as soon as possible. The Company s plans to seek approval for Twirla are dependent on its planned meeting with the FDA on the parameters of the wear study for Twirla and its ability to reach agreement with the FDA on the scope and size of the study. The Company can make no assurances that it can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If the Company is unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require the Company to reformulate Twirla and conduct additional clinical or bioequivalence studies before it can resubmit the Twirla NDA.

The Company also announced a reduction in its workforce and reductions in other planned operating expenses (see Note 9) as it pursued formal dispute resolution. As a result of these planned cost reductions, the Company believes that its cash and cash equivalents as of September 30, 2018, will be sufficient to meet its projected operating requirements into the second quarter of 2019 which include an estimate of the costs to complete a comparative wear study. The timing and cost of the Twirla wear study may affect the Company s ability to funds its operations into the second quarter of 2019. The Company anticipates providing a further business update, which will review its planned resubmission timeline, cash position and funding requirements after it agrees with the FDA on the parameters of the wear study for Twirla. The Company will require additional capital to fund operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting, the resumption and completion of its commercialization plan for Twirla, which primarily includes the validation of the Company s 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, 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 anticipates it will continue to incur net losses for the foreseeable future and the Company s ability to continue operations for the remainder of the second quarter of 2019 and beyond 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.

As of September 30, 2018, the Company had cash and cash equivalents of $16.9 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 additional capital and/or implement the various strategic alternatives discussed above. The Company cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company s current stockholders will experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company then may be unable to complete the development of Twirla, and may also be required to further cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

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Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2018

(in thousands, except share and per share data)

The unaudited financial statements as of September 30, 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 September 30, 2018 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

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 reflect 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 and nine months ended September 30, 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.

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.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment,* the Company s policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset

Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2018

(in thousands, except share and per share data)

may not be recoverable. Management does not believe that there has been any impairment of the carrying value of any long-lived assets as of September 30, 2018.

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 September 30, 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 September 30, 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.

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.

Agile Therapeutics, Inc.

Notes to Unaudited Financial Statements

September 30, 2018

(in thousands, except share and per share data)

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 and nine months ended September 30, 2018 and 2017, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	September 30,	
	2018	2017
Common stock warrants	242,779	242,779
Unvested restricted stock units	147,554	264,361
Common stock options	5,687,901	3,798,951
Total	6,078,234	4,306,091

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. While the Company is currently evaluating the impact of adopting ASU 2016-02, the Company preliminarily estimates recording a lease asset and lease liability of approximately $0.3 million on its balance sheets, with no material impact on its statements of operations.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* This ASU eliminates the requirement to consider down round features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity s own stock. ASU 2017-11 is effective for annual periods beginning after December 31, 2018. Early adoption is permitted. The Company does not believe the impact of the adoption of ASU 2017-11 will have a material impact 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.

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In June 2018, the FASB issued ASU No. 2018-07, *Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting*, which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. This ASU becomes effective in the first quarter of fiscal year 2019 and early adoption is permitted, but no earlier than an entity s adoption date of ASC 606. The Company elected to early adopt this ASU during the third quarter of 2018 and adoption of ASU No. 2018-07 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 participants 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.

The following table sets forth the Company s financial instruments measured at fair value by level within the fair value hierarchy as of September 30, 2018 and December 31, 2017.

	Level 1	Level 2	Level 3
September 30, 2018			
Assets:			
Cash and cash equivalents	$ 16,818	$	$
Total assets at fair value	$ 16,818	$	$
Liabilities:			
Common stock warrants	$	$	$
Total liabilities at fair value	$	$	$

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	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 September 30, 2018 include (i) volatility (70.0%), (ii) risk free interest rate of 2.59% (estimated using treasury bonds with a 1.25 year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($0.37) and (v) expected life (1.25 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	(29)
Ending balance at September 30, 2018	$

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.

4. Prepaid Expenses

Prepaid expenses consist of the following:

	September 30, 2018		December 31, 2017	
Prepaid clinical trial expense	$		$	205
Prepaid insurance		566		388
Other		165		169
Total prepaid expenses	$	731	$	762

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5. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2018	December 31, 2017
Employee bonuses	$ 820	$ 215
Accrued interest payable	571	451
Accrued restructuring costs (see Note 9)	386	
Accrued professional fees and other	245	186
Total accrued liabilities	$ 2,022	$ 852

6. Loan and Security Agreements

Hercules Capital, Inc.

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

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

The First Amendment 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 the 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 September 30, 2018 and December 31, 2017, the Company had outstanding borrowings of $5.9 million and $10.9 million, respectively, related to the Hercules Loan Agreement which is recorded on the balance sheet in loan payable, current portion. As of September 30, 2018, the fair value of Term Loan approximates its carrying value.

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 to the outstanding principal balance, the Company is required to make an end of term

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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.

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 $91 and $289, for the three and nine months ended September 30, 2018, respectively and $459 and $1,509, for the three and nine months ended September 30, 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. The 2015 Shelf Registration Statement expired on June 30, 2018 and the Company no longer has an active Shelf Registration Statement.

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. Given the uncertainty of the achievement of the performance goals during the performance period, the Company has not recorded compensation expense related to these awards for the three and nine months ended September 30, 2018.

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Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Research and development	$ 286	$ 309	$ 975	$ 889
General and administrative	435	658	1,852	1,838
Total	$ 721	$ 967	$ 2,827	$ 2,727

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. Restructuring Costs

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

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

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

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

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A summary of accrued restructuring costs, included as a component of accrued liabilities on the Company s unaudited September 30, 2018 balance sheet is as follows:

	December 31, 2017	Charges	Payments	September 30, 2018
Accrued severance	$	380	(329)	51
Accrued retention bonus		335		335
Total	$	$ 715	$ (329)	$ 386

10. 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 September 30, 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.

Recent Regulatory History

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 specifications 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. The 2017 CRL further 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.

In November 2017 and December 2017, Corium provided the FDA with responses to each of the observations made during the FDA s facility inspection. In April 2018, we 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, and we announced the content of the official minutes from the meeting in May 2018, which included FDA s conclusion that the *in vivo* adhesion properties of Twirla were not adequate to support approval of the NDA and that we needed to reformulate Twirla. The FDA also said it anticipates discussing the safety and efficacy of Twirla at an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The FDA also provided guidance on the path forward for addressing the manufacturing quality control test method issues related to Twirla and informed us that whether these issues have been adequately addressed would be subject to review by the FDA when we resubmit our Twirla NDA.

In June 2018, we announced we had submitted a formal dispute resolution request, or FDRR, with the FDA for Twirla. The dispute pertained to the determination from the FDA s reviewing Division of Bone, Reproductive and Urologic Products, or DBRUP, that concerns surrounding the *in vivo* adhesion properties of Twirla prevent the approval of the NDA and could not be addressed through our proposed patient compliance programs. By submitting the FDRR, we availed the Company of the FDA s established appeal process whereby disagreements with conclusions reached by a reviewing Division within the FDA are reviewed above the Division level. The initial FDRR we submitted in June 2018 was denied by the Office of Drug Evaluation III, or ODE III, on July 20, 2018. We then escalated our appeal to the Office of New Drugs, or OND.

In October 2018, OND formally denied our appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that we reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by DBRUP in the April 2018 Type A meeting. Specifically, OND suggested that we conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result

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is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that we first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. The wear study suggested by OND to address adhesion provides a path forward for resubmission of the NDA for Twirla but is not intended to address efficacy. Rather, if the wear study is successful, Twirla s safety and efficacy, including the Pearl Index that FDA noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after we resubmit the NDA for Twirla. This is an issue that the FDA plans to bring to Advisory Committee after the adhesion issue has been resolved. We have submitted a request for a Type A meeting and plan to discuss the specifics of the proposed wear study with the FDA at that meeting. Our plans to seek approval for Twirla are dependent on our planned meeting with the FDA on the parameters of the wear study for Twirla and our ability to reach agreement with the FDA on the scope and size of the study. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the 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 anticipated resubmission before approval can be granted. 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.

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $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 $1.5 million and $7.9 million for the three and nine months ended September 30, 2018, respectfully, and $3.2 million and $11.7 million for the three and nine months ended September 30, 2017, respectfully. We anticipate that a portion of our operating expenses will continue to be related to research and development as we continue to develop Twirla. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of September 30, 2018 and December 31, 2017 respectively, we had $16.9 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. The period during which the additional tranche of $8.5 million may be drawn has expired and therefore the $8.5 million can no longer be drawn by us. 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

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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.

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.

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 $3.8 million and $16.0 million for the three and nine months ended September 30, 2018, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we seek the approval of our NDA for Twirla, which will now include designing and implementing the wear study of Twirla and Xulane suggested by the FDA, 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.

Going Concern

We believe that our cash and cash equivalents as of September 30, 2018, will be sufficient to meet our projected operating requirements into the second quarter of 2019 which include an estimate of the costs to complete a comparative wear study. The timing and cost of the Twirla wear study may affect our ability to fund our operations into the second quarter of 2019. We anticipate providing a further business update, which will review our planned resubmission timeline, cash position, and related funding requirements, after we agree with the FDA on the parameters of the wear study for Twirla. We will require additional capital to fund our operating needs for the remainder of the second quarter of 2019 and beyond including, among other items, preparation for an anticipated Advisory Committee meeting, 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.

Pursuant to the receipt of the 2017 CRL, and the delay in the approval timeline for Twirla, our ability to continue operations for the remainder of the second quarter of 2019 and beyond 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 September 30, 2018, we had cash and cash equivalents of $16.9 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 additional 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 will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we then may be unable to complete the development of Twirla, and may also be required to further cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The unaudited financial statements as of September 30, 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

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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.

We do not own any manufacturing facilities and rely on Corium for all aspects of the manufacturing of Twirla. We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the 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 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 additional capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

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

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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 will likely decrease as compared with our 2017 research and development expenses as we completed our pursuit of formal dispute resolution, determine a regulatory path forward for the resubmission of our NDA for Twirla, and plan and initiate a comparative wear study of Twirla and Xulane. Research and development expenses in 2018 consist primarily of those costs associated with the continued development and refinement of our commercial manufacturing process, costs associated with the formal dispute resolution process, planning and initiating a comparative wear study, and preparation and resubmission of the NDA for Twirla. In response to the 2017 CRL, we have 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. Research and development expenses in 2018 include support for the formal dispute resolution process, planning and initiating a comparative wear study of Twirla and Xulane, preparing the resubmission of our NDA, and will also go toward the qualification and validation of our commercial manufacturing process. For the three months ended September 30, 2018 and 2017, our research and development expenses were approximately $1.5 million and $3.2 million, respectively. For the nine months ended September 30, 2018 and 2017, our research and development expenses were approximately $7.9 million and $11.7 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended September 30,		(In thousands) Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Clinical development	$ 160	$ 588	$ 591	$ 2,609
Regulatory	162	95	497	1,191
Personnel related	501	675	1,827	2,129
Manufacturing - commercialization	403	1,379	3,894	4,082
Manufacturing	37	129	137	794
Stock-based compensation	286	309	975	889
Total research and development expenses	$ 1,549	$ 3,175	$ 7,921	$ 11,694

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.

We anticipate providing a further business update, which will review our planned resubmission timeline, cash position and related funding requirements, after we agree with the FDA on the parameters of the wear study for Twirla. The timing and outcome of the Twirla wear study may affect the timing of our NDA resubmission. 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,

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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.

General and Administrative Expenses

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

For the three months ended September 30, 2018 and 2017, our general and administrative expenses totaled approximately $1.8 million and $3.5 million, respectively. For the nine months ended September 30, 2018 and 2017, our general and administrative expenses totaled approximately $7.2 million and $9.1 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. In which case, 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.

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Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

	Three months ended September 30, 2018	2017	Change
Operating expenses:			
Research and development	$ 1,549	$ 3,175	$ (1,626)
General and administrative	1,767	3,526	(1,759)
Restructuring costs	299		299
Total operating expenses	3,615	6,701	(3,086)
Other income (expense)			
Interest income	91	78	13
Interest expense	(268)	(459)	191
Change in fair value of warrants		(20)	20
Total other income (expense), net	(177)	(401)	224
Loss before benefit from income taxes	(3,792)	(7,102)	3,310
Benefit from income taxes			
Net loss	$ (3,792)	$ (7,102)	$ 3,310

Research and development expenses. Research and development expenses decreased by $1.6 million, or 51%, from $3.2 million for the three months ended September 30, 2017 to $1.6 million for the three months ended September 30, 2018. This decrease in research and development expenses was primarily due to the following:

- a decrease in manufacturing commercialization expenses of $1.0 million for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. This decrease reflects reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL. Costs related to the qualification, validation and manufacture of Twirla will be recorded as research and development expenses until we receive approval of our NDA for Twirla;

- a decrease in clinical development expenses of $0.4 million for the three months ended September 30, 2018 as compared to the three months ended September 30, 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 September 30, 2018; and

- a decrease in personnel-related expenses of $0.2 million for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts.

General and administrative expenses. General and administrative expenses decreased by $1.7 million, or 50%, from $3.5 million for the three months ended September 30, 2017 to $1.8 million for the three months ended September 30, 2018. This decrease in general and administrative expense was primarily due to:

- a decrease in commercial development expense of $1.2 million for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. This decrease relates to the suspension of

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our pre-commercialization activities such as brand building, advocacy and consulting as a result of the receipt of the 2017 CRL;

- a decrease in professional fees expense of $0.3 million for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. This decrease is primarily the result of a reduction in the use of consultants and lower legal and patent-related costs; and

- a decrease in stock compensation expense of $0.2 million for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts.

Restructuring costs. In June 2018, we announced a reduction in our workforce, which resulted in the termination of several employees primarily from our commercial and clinical teams, representing approximately thirty percent of our employees. This workforce reduction, along with other reductions in planned operating expenses was designed to preserve cash while we pursued formal dispute resolution with the FDA for Twirla and as we determine the regulatory path forward for the resubmission of our NDA for Twirla. In addition, in June 2018, we also announced that we had adopted a retention plan to provide (i) cash retention payments to be made to all remaining employees in order to induce such employees to remain employed by us through December 31, 2018 and (ii) stock option grants to all remaining employees in order to induce such employees to remain employed by us through December 31, 2019. Restructuring costs of $0.3 million for the three months ended September 30, 2018 represent costs related to the accrual of the retention bonus. All severance-related costs were accrued as of June 30, 2018.

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 September 30, 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 42%, from $0.5 million for the three months ended September 30, 2017 to $0.3 million for the three months ended September 30, 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 September 30, 2018 as compared to the three months ended September 30, 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 of the price of the underlying stock. 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.

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Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine months ended September 30, 2018	Nine months ended September 30, 2017	Change
Operating expenses:			
Research and development	$ 7,921	$ 11,694	$ (3,773)
General and administrative	7,173	9,130	(1,957)
Restructuring costs	715		715
Total operating expenses	15,809	20,824	(5,015)
Other income (expense)			
Interest income	289	187	102
Interest expense	(955)	(1,509)	554
Change in fair value of warrants	29	82	(53)
Total other income (expense), net	(637)	(1,240)	603
Loss before benefit from income taxes	(16,446)	(22,064)	5,618
Benefit from income taxes	477		477
Net loss	$ (15,969)	$ (22,064)	$ 6,095

Research and development expenses. Research and development expenses decreased by $3.8 million, or 32%, from $11.7 million for the nine months ended September 30, 2017 to $7.9 million for the nine months ended September 30, 2018. This decrease in research and development expenses was primarily due to the following:

- a decrease in clinical development expenses of $2.0 million for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 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 nine months ended September 30, 2018;

- a decrease in regulatory expenses of $0.7 million for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. This decrease primarily relates to reduction of regulatory activity during the nine months ended September 30, 2018 as compared the nine months ended September 30, 2017. Regulatory expenses for the nine months ended September 30, 2017 included external costs associated with the preparation of our NDA resubmission and response to the FDA s CRL received by us in February 2013;

- a decrease in manufacturing commercialization expenses of $0.5 million for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. This decrease reflects reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL. Costs related to the qualification, validation and manufacture of Twirla will be recorded as research and development expenses until we receive approval of our NDA for Twirla; and

- a decrease in personnel-related expenses of $0.3 million for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts.

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General and administrative expenses. General and administrative expenses decreased by $1.9 million, or 21%, from $9.1 million for the nine months ended September 30, 2017 to $7.2 million for the nine months ended September 30, 2018. This decrease in general and administrative expense was primarily due to:

- a decrease in commercial development expense of $1.8 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. This decrease relates to the suspension of our pre-commercialization activities such as brand building, advocacy and consulting as a result of the receipt of the 2017 CRL;

- a decrease in professional fees expense of $0.5 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. This decrease is primarily the result of a reduction in the use of consultants and lower legal and patent-related costs; and

- an increase in personnel costs of $0.4 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. This increase relates to the addition of personnel during the second half of 2017 to help prepare for launch of Twirla, if approved.

Restructuring costs. In June 2018, we announced a reduction in our workforce, which resulted in the termination of several employees primarily from our commercial and clinical teams, representing approximately thirty percent of our employees. This workforce reduction, along with other reductions in planned operating expenses was designed to preserve cash while we pursued formal dispute resolution with the FDA for Twirla and as we determine the regulatory path forward for the resubmission of our NDA for Twirla. In addition, in June 2018, we also announced that we had adopted a retention plan to provide (i) cash retention payments to be made to all remaining employees in order to induce such employees to remain employed by us through December 31, 2018 and (ii) stock option grants to all remaining employees in order to induce such employees to remain employed by us through December 31, 2019. Restructuring costs of $0.7 million for the nine months ended September 30, 2018 represent $0.4 million of severance-related costs and $0.3 million of costs related to the accrual of the retention bonus.

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 nine months ended September 30, 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 $0.5 million, or 37%, from $1.5 million for the nine months ended September 30, 2017 to $1.0 million for the nine months ended September 30, 2018. This decrease is primarily the result of a decrease in the principal outstanding under our term loan with Hercules for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 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 of the price of the underlying stock. During the nine months ended September 30, 2018, we reported income of $29 thousand related to the decrease in the fair value of the warrants as compared to income of $82 thousand for the nine months ended September 30, 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 nine months ended September 30, 2018, we received $0.5 million from the sale of New Jersey state Net Operating Loss Carryovers, or NOLs, as part of the Technology and Business Tax Certificate Program, or the Program. We did not receive any payments under the Program during the nine months ended September 30, 2017. The Program enables approved biotechnology companies to sell their unused NOLs and unused Research and Development Tax Credits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The New Jersey Economic Development Authority and the New Jersey Department of the Treasury s Division of Taxation administer the Program. We intend to use the proceeds from the sale for working capital purposes. We have reached the maximum lifetime benefit of $15.0 million under the Program and is no longer eligible to participate in the Program.

Liquidity and Capital Resources

At September 30, 2018, we had cash and cash equivalents totaling $16.9 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:

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net cash used in operating activities	$ (13,759)	$ (18,750)
Net cash used in investing activities	(318)	(771)
Net cash (used in) provided by financing activities	(4,949)	14,577
Net decrease in cash and cash equivalents	$ (19,026)	$ (4,944)

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 lead product candidate, Twirla, was being developed. Net cash used in operating activities was $13.8 million for the nine months ended September 30, 2018 and consisted primarily of a net loss of $16.0 million, which was offset by non-cash stock-based compensation expense of $2.8 million, non-cash interest expense of $0.4 million and a decrease in working capital of $1.0 million. Net cash used in operating activities was $18.8 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $22.1 million which was offset by non-cash stock-based compensation expense of $2.7 million and non-cash interest expense of $0.5 million. Cash used in operations in 2018 has been offset, in part, by the proceeds received from the sale of New Jersey NOLs under the Program. 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.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2018 and 2017 was $0.3 million and $0.8 million, 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 nine months ended September 30, 2018 was $4.9 million which primarily represented principal payments under the Hercules Loan Agreement, which began on February 1, 2017. Net cash provided by financing activities for the nine months ended September 30, 2017 was $14.6 million which primarily represented net proceeds of $18.5 million received from our follow-on offering of common stock offset, in part, by principal payments under the Hercules Loan Agreement of $4.1 million.

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Funding Requirements and Other Liquidity Matters

Since 2012 we have sought regulatory approval for Twirla and, in the process, received two complete response letters from the FDA in connection with our NDA for Twirla, which have included requests to conduct additional studies and gather additional information on our manufacturing process for Twirla. 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. Since then we have engaged with the FDA to seek clarity on a regulatory path for the potential approval of Twirla culminating in a formal dispute resolution request to the FDA. In October 2018, the FDA s Office of New Drugs formally denied our appeal and provided a path forward for resubmission of the NDA for Twirla that will require us to conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, we plan to resubmit our NDA with the results from this wear study along with our other responses to the 2017 CRL. The FDA has informed us that in connection with the review of the Twirla NDA, the FDA plans to bring the issue of Twirla s safety and efficacy to an Advisory Committee. We have submitted a request for a Type A meeting and plan to discuss the specifics of the proposed wear study with the FDA at that meeting. Our plans to seek approval for Twirla are dependent on our planned meeting with the FDA on the parameters of the wear study for Twirla and our ability to reach agreement with the FDA on the scope and size of the study. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the Twirla NDA.

In addition to the reductions in planned operating expenses we began implementing in January 2018, we reduced our workforce by approximately thirty percent in June 2018 as we pursued formal dispute resolution and a path forward for the resubmission of our NDA for Twirla. As a result of these planned cost reductions, we believe that our cash and cash equivalents as of September 30, 2018, will be sufficient to meet our projected operating requirements into the second quarter of 2019 which include an estimate of the costs to complete a comparative wear study. The timing and cost of the Twirla wear study may affect our ability to fund our operations into the second quarter of 2019. We anticipate providing a further business update, which will review our planned resubmission timeline, cash position, and related funding requirements, after we agree with the FDA on the parameters of the wear study for Twirla. We will require additional capital to fund our operating needs for the remainder of the second quarter of 2019 and beyond including, among other items, preparation for an anticipated Advisory Committee meeting, 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 cannot assure you that the FDA will approve Twirla, or that we along with Corium, our third-party manufacturer, will be able to complete validation of our commercial manufacturing successfully and in a timely manner.

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:

- conduct the wear study of Twirla and Xulane suggested by the FDA;

- need to reformulate Twirla if the results of the wear study do not support resubmission of our Twirla NDA and we are required to conduct additional studies;

- prepare for and participate in an Advisory Committee review of the safety and efficacy of Twirla;

- seek marketing approval for Twirla in the United States;

- 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;

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- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;

- maintain, leverage and expand our intellectual property portfolio; and

- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We may also need to raise additional funds sooner if we choose to accelerate components of our commercial plan or we encounter any unforeseen events that affect our current business plan or we may choose to raise additional funds to provide us with additional working capital. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms or are unable to enter into strategic collaborations, we then may be unable to complete the development of Twirla, and may also be required to further cut operating costs, forgo future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. Because of the numerous risks and uncertainties associated with 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 the wear study of Twirla and Xulane suggested by the FDA;

- 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.

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2018 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Term loan	$ 6,682	$ 6,682	$	$	$
Operating lease	441	200	241		
Total	$ 7,123	$ 6,882	$ 241	$	$

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. The period during which the additional tranche of $8.5 million may be drawn has expired and therefore the $8.5 million can no longer be drawn by us. 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.

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.

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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). The 2015 Shelf Registration Statement expired on June 30, 2018 and we no longer have an active 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.

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 $16.9 million and $35.9 million at September 30, 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

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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 and nine months ended September 30, 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 provided a path forward to resubmit the Twirla NDA, which involves a comparative wear study of Twirla and Xulane. Failure of the wear study to support resubmission of our Twirla NDA, and/or our failure to resubmit the Twirla NDA and to receive regulatory approval of Twirla would have a material adverse effect on our business and would likely 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 requires 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 on 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. In accordance with the FDA s advice and comments, we conducted an additional Phase 3 clinical trial, the SECURE clinical trial, which was completed in December 2016. In June 2017, we resubmitted our Twirla NDA.

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. The 2017 CRL further 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 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, many of which were 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 Twirla efficacy, cycle control, and safety. Finally, the 2017 CRL recommends that we address the implications of clinical trial subject patch compliance and the high withdrawal and dropout rates for real world use. The 2017 CRL does not identify any specific issues relating to the safety of Twirla. In November 2017 and December 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 which we do not know whether the FDA will find acceptable.

At our request, the FDA s Division of Bone, Reproductive and Urologic Products, or DBRUP, had a Type A meeting with us on April 16, 2018 to discuss the 2017 CRL and the regulatory path for approval of Twirla. In its official minutes, the FDA informed us that, in order to address concerns surrounding *in vivo* adhesion, we needed to reformulate the transdermal system, conduct a formal *in vivo* adhesion study with the new formulation, and demonstrate bioequivalence to the data and information in the original formulation. The FDA also said that it anticipates discussing the safety and efficacy of Twirla at an Advisory Committee meeting to obtain input on whether the benefits of Twirla outweigh the risks. The FDA also provided guidance on the path forward for addressing the manufacturing quality control test method issues related to Twirla and informed us that whether these issues have been adequately addressed would be subject to review by the FDA when we resubmit our Twirla NDA.

We disagreed with the FDA s conclusions regarding the *in vivo* adhesion properties of Twirla and the need for product reformulation, and we submitted a formal dispute resolution request, or FDRR, to the FDA. In October 2018, the FDA s Office of New Drugs, or OND, formally denied our appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that we reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by DBRUP. Specifically, OND suggested that we conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that we first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. The wear study suggested by OND to address adhesion provides a path forward for resubmission of the NDA for Twirla but is not intended to address efficacy. Rather, if the wear study is successful, Twirla s safety and efficacy, including the Pearl Index that FDA noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after we resubmit the NDA for Twirla. This is an issue that the FDA plans to bring to Advisory Committee after the adhesion issue has been resolved. We have submitted a request for a Type A meeting and plan to discuss the specifics of the proposed wear study with the FDA as soon as possible. Our plans to seek approval for Twirla are dependent on our planned meeting with the FDA on the parameters of the wear study for Twirla and our ability to reach agreement with the FDA on the scope and size of the study. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the Twirla NDA. Even if we do successfully complete the wear study, there is no guarantee that the FDA will find Twirla to have an adequate risk benefit profile or determine that its manufacturing, specifications, and test methods are satisfactory.

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. Upon resubmission, there can be no assurance that we will address the outstanding FDA questions and comments in a manner sufficient for approval in the U.S, as we will not only need to conduct the wear study but we will also need to address the FDA s other 2017 CRL questions and comments. If we are unable to sufficiently address the FDA s questions and comments, it would adversely impact our NDA, and ultimately, approval of Twirla. Even if we resolve the adhesion issue, and the FDA agrees that the wear study of Twirla and Xulane demonstrates adequate Twirla adhesion, the FDA, and an FDA Advisory Committee, may still determine that Twirla s potential benefits do not outweigh its risks and therefore are not sufficient to support the approval of Twirla.

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Moreover, the FDA must determine that Corium s manufacturing facilities meet certain FDA requirements for product manufacturing, before granting product approval and before we can use them in the commercial manufacture of our products. We cannot assure you that Corium s responses to the objectionable conditions found during the FDA s facility inspection will adequately address the issues communicated by the FDA in the 2017 CRL. 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, including commercial pre-launch and manufacturing validation activities, pending our ability to address the 2017 CRL and receive approval of Twirla, which reduced our cash outlay. We further reduced expenditures when, in June 2018, we announced a reduction in our workforce representing approximately thirty percent of our employees. This workforce reduction, along with other reductions in our planned operating expenses, was designed to reduce operating expenses and preserve cash while we pursued formal dispute resolution. We continue to maintain expenditures relating to completing the development and seeking regulatory approval of Twirla, which will now include designing and implementing the comparative wear study of Twirla and Xulane suggested by the FDA. We will require additional funding to complete the commercial validation of the manufacturing process and commercial launch for Twirla. Our planned timeline for seeking approval of Twirla and our ability to fund our operations through the period of time necessary to receive approval of Twirla, if at all, could be adversely affected based on the outcome of our expected meeting with the FDA on the parameters of the wear study, including primarily the scope, size and cost of the study, any or all of which may require us to seek additional funding. 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 September 30, 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 September 30, 2018, we had cash and cash equivalents of $16.9 million. After the reduction in our workforce, representing approximately thirty percent of our employees, along with other reductions in planned operating expenses, we believe that our cash and cash equivalents as of September 30, 2018, will be sufficient to meet our projected operating requirements into the second quarter of 2019 which include an estimate of the costs to complete a comparative wear study. 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, the formal dispute resolution process with the FDA, the suggestion by the FDA that we conduct a comparative wear study with Twirla and Xulane, the outcome of which cannot be guaranteed, and the subsequent 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 additional capital and/or implement the various strategic alternatives discussed above. We

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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 then may be unable to complete the development of Twirla and may also be required to further 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, and such approval or approvals may never be granted or may be substantially delayed if regulatory authorities require additional time or studies to assess the safety and efficacy of our product candidates.

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, or CMC, for the product. The FDA may further inspect our manufacturing facilities to ensure that the facilities can manufacture our product candidates and our products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission, 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, reformulate the product, address issues with our manufacturing process or facilities, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, or if we are unable to successfully complete a comparative wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion and are required to reformulate Twirla before resubmitting the Twirla NDA, or if the FDA, an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval we may never receive marketing approval or we would incur delays in the marketing approval process and increased costs which may require us to expend more resources than we have available. 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, and 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 and could lead to additional costs and delays. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

For instance, we have sought regulatory approval for Twirla since 2012 and, in the process, received two complete response letters from the FDA in connection with our NDA for Twirla, which have included requests to conduct additional studies and gather and develop additional information on our manufacturing process, test

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methods, and specifications for Twirla. We initially 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 CMC information, which needed to be addressed before approval could be granted. We gathered the requested information and, in accordance with the FDA s advice and comments, conducted an additional Phase 3 clinical trial, the SECURE clinical trial, which was completed in December 2016. Although we met with the FDA in October 2013 to discuss the SECURE trial as requested in the 2013 CRL and received substantial written comments from the FDA in subsequent interactions, we did not seek and did not obtain agreement with the FDA on a special protocol assessment regarding the SECURE clinical trial. Based on the results of the SECURE clinical trial and additional information relating to the manufacture of Twirla, we resubmitted our NDA in June 2017. Our NDA resubmission in 2017 was intended to be a complete response to the 2013 CRL. It included efficacy and safety data from the SECURE clinical trial, the requested manufacturing information, and a summary response to 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 our third-party manufacturer, Corium, for the Twirla NDA must be resolved. The 2017 CRL further 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 we assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial and determine whether there is an adverse impact on the product performance. Finally, the 2017 CRL recommends that we address the implications of clinical trial subject patch compliance and the high withdrawal and dropout rates. The 2017 CRL does not identify any specific issues relating to the safety of Twirla. In addition, in November 2017 and December 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 which we do not know whether the FDA will find acceptable.

At our request, the FDA s Division of Bone, Reproductive and Urologic Products had a Type A meeting with us on April 16, 2018 to discuss the deficiencies in the Twirla NDA identified in the 2017 CRL and the regulatory path for approval of Twirla. In its official minutes, the FDA informed us that to address concerns surrounding *in vivo* adhesion we needed to reformulate the transdermal system, conduct a formal *in vivo* adhesion study with the new formulation, and demonstrate bioequivalence to the data and information in the original formulation. The FDA also said it anticipates discussing the safety and efficacy of Twirla at an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The FDA also provided guidance on the path forward for addressing the manufacturing quality control test method issues related to Twirla, and informed us that whether these issues have been adequately addressed would be subject to review by the FDA when we resubmit our Twirla NDA

We disagreed with the FDA s conclusions regarding the *in vivo* adhesion properties of Twirla and the need for product reformulation, and we submitted a formal dispute resolution request, or FDRR, to the FDA. In October 2018, the FDA s Office of New Drugs, or OND, formally denied our appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that we reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by DBRUP. Specifically, OND suggested that we conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. OND has recommended that we first meet with DBRUP to gain agreement on the specific design and success criteria of a wear study for Twirla. The wear study suggested by OND to address adhesion provides a path forward for resubmission of the NDA for Twirla but is not intended to address efficacy. Rather, if the wear study is successful, Twirla s safety and efficacy, including the Pearl Index that OND noted is substantially higher than other previously approved combined hormonal contraceptives, will need to be reviewed by FDA after we resubmit the NDA for Twirla. This is an issue that the FDA plans to bring to Advisory Committee after the adhesion issue has been resolved. We have submitted a request for a Type A meeting and plan to discuss the specifics of the proposed wear study with the FDA as soon as possible. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete a wear trial of

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Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the Twirla NDA. Even if we do successfully complete the wear study, there is no guarantee that the FDA will find Twirla to have an adequate risk benefit profile or determine that its manufacturing, specifications, and test methods are satisfactory.

We anticipate providing a further business update, which will review our planned resubmission timeline, after we agree with the FDA on the parameters of the wear study for Twirla. The timing and outcome of the Twirla wear study will impact the timing of our NDA resubmission. If we are unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the 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. Upon resubmission, there can be no assurance that we will address the outstanding FDA questions in a manner sufficient for approval in the U.S.

Moreover, the FDA must determine that Corium s manufacturing facilities meet certain FDA requirements for product manufacturing, before granting product approval and before we can use them in the commercial manufacture of our products. We cannot assure you that Corium s responses to the objectionable conditions found during the FDA s facility inspection will adequately address the issues communicated by the FDA in the 2017 CRL. We also expect that the FDA will re-inspect the Corium facilities during its review of our planned resubmission before approval can be granted. 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 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, the FDA could withhold approval or 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.

In connection with our planned resubmission of the Twirla NDA in response to the 2017 CRL, we cannot predict whether regulators will agree with our conclusions regarding the results of the SECURE clinical trial or any clinical trials we have conducted to date or will conduct prior to resubmitting the Twirla NDA, including whether our data are reliable and generalizable, demonstrate adequate adhesion properties and/or demonstrate adequate safety and efficacy sufficient for approval. For example, based on our analysis of the SECURE clinical trial 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 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 30 kg/m^2). The October 2018 FDRR decision letter did not reach a decision on efficacy. Nonetheless, OND did communicate that upon its initial review, our analyses of population differences and study design do not seem to support our conclusions regarding efficacy results from SECURE. However, 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. A fuller assessment of the clinical outcomes from the SECURE trial, and specifically the safety and efficacy of Twirla, will need to be conducted by the FDA and a likely Advisory Committee when or if we resubmit our NDA for Twirla.

The FDA indicated in the official minutes of our end of review Type A Meeting and in its October 2018 FDRR decision letter that it anticipates reviewing the safety and efficacy of Twirla during an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The Advisory Committee may recommend non-approval for Twirla or may recommend approval with label restrictions. Even if the Advisory Committee determines that the benefits of Twirla outweigh its risks and recommends approval, the FDA could still conclude that the Pearl Index is too high to demonstrate efficacy and an adequate risk/benefit profile for either the overall

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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.

We may be unable to initiate or complete development of Twirla and our other potential 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, require us to conduct a comparative wear study between Twirla and Xulane that is significantly larger in scope and size than we are currently planning, or require us to reformulate the product, 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. In fact, we may never receive 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.

In addition to the factors discussed above, delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many other factors, including:

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

- 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;

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

- 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;

- 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;

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

- 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;

- 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 clinical trial sites;

- 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;

- Failure of manufacturers to comply with FDA s or comparable regulatory authorities requirements for the manufacture of products and product candidates;

- FDA or comparable regulatory authority determinations that our manufacturing processes, specifications, or tests are not sufficient or acceptable;

- FDA or comparable regulatory authority determinations that our clinical trials were not properly conducted or that such conduct did not comply with regulatory requirements;

- Our inability 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.

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 potential product candidates, we may not obtain such approvals on a timely basis, if at all.

The process to develop and obtain regulatory approval for 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 boxed warnings, require expensive and time-consuming

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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 other marketed hormonal contraceptive products, which includes 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 boxed warnings or contraindications, as well as additional labeled limitations, such as limitations on the use of Twirla for women based on BMI or weight. 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 if 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.

The FDA has disagreed 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.

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 product performance. The FDA also recommended we address the implications of clinical trial subject patch compliance and the high 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 met with the FDA at a Type A meeting to discuss the deficiencies identified in the 2017 CRL and received the official minutes of that meeting on May 15, 2018. Among other points, the FDA also indicated in the official minutes and also in its October 2018 FDRR decision letter that, if we are able to demonstrate an adequate Twirla adhesion profile the FDA anticipates reviewing the safety and efficacy of Twirla, including the Pearl Index that the FDA has noted is substantially higher than other previously approved combined hormonal contraceptives, during an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The October 2018 FDRR decision letter did not reach a decision on efficacy. Nonetheless, OND did communicate that upon its initial review, our analyses of population differences and study design do not seem to support our conclusions regarding efficacy results from SECURE. As noted above, a fuller assessment of the clinical outcomes from the SECURE trial, and specifically the safety and efficacy of Twirla, will need to be conducted by the FDA and a likely Advisory Committee when or if we resubmit our NDA for 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. The Advisory Committee may recommend non-approval for Twirla or may recommend approval with label restrictions. Even if the Advisory Committee determines that the benefits of Twirla outweigh its risks for either the full study population or a subgroup, and recommends approval, the FDA could still decline to approve the product candidate. By example, 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. FDA may 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. FDA

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may, accordingly, not approve Twirla or only approve the product candidate for use in a specific subgroup, such as the non-obese study population. FDA may also decline to approve Twirla on any other basis.

Negative or inconclusive results of a clinical trial or difference of opinion or negative Advisory Committee outcome 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 has the authority to re-inspect SECURE clinical trial sites as part of a review of an NDA, and the FDA may provide review commentary at any time during the resubmission and review process, either of 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.

There is no guarantee that the data obtained from the SECURE clinical trial or any other clinical trial will be supportive of, or guarantee, or result in our successfully obtaining timely FDA approval of Twirla for a commercially viable indication, if at all. 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. When we do resubmit, the FDA could determine that the trial did not meet its objectives, or the FDA could still have concerns about the conduct of the SECURE clinical trial, including regarding discontinuance of subjects from the trial, which was a factor mentioned in the 2017 CRL. While we designed the protocol for the SECURE clinical trial in consultation with the FDA 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. Moreover, we cannot guarantee that we will resubmit our Twirla NDA for numerous reasons, including if our wear study is unsuccessful, if the study, as a result of its parameters, size, and scope, is more burdensome than we are prepared to conduct, or if we believe we are unable to respond to the issues raised in the 2017 CRL.

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. 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. However, upon any future NDA resubmission, the FDA may find that the Twirla Pearl Index does not support a satisfactory benefit/risk profile to permit product approval.

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.

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

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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, when combined with a wear study, are not supportive of approval because of a lack of adequate adhesion, efficacy, or safety. By example, the 2017 CRL raised FDA questions and comments regarding the results of the SECURE trial, as discussed elsewhere in this quarterly report. The FDA has indicated in its correspondence with us and its October 2018 FDRR decision letter that it anticipates reviewing the safety and efficacy of Twirla, including the Pearl Index that FDA has noted is substantially higher than other previously approved combined hormonal contraceptives, during an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The Advisory Committee may recommend non-approval for Twirla or may recommend approval with label restrictions. Even if the Advisory Committee determines that the benefits of Twirla outweigh its risks and recommends approval, the FDA could still 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, and may decline to approve the Twirla NDA or require us to repeat the trial or conduct additional clinical trials to assess Twirla s safety and efficacy prior to obtaining approval. 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.

In addition, in its October 2018 FDRR decision letter, the FDA suggested that we conduct a comparative wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, the FDA stated that the study would support the conclusion of adequate Twirla adhesion. We have submitted a request for a Type A meeting and plan to discuss the specifics of the proposed wear study with the FDA as soon as possible. We can make no assurances that we can successfully complete the wear study suggested by the FDA or that the results will demonstrate adequate adhesion of Twirla. If we are unable to successfully complete a wear trial of Twirla and Xulane to support the conclusion of adequate Twirla adhesion, the FDA will likely require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can resubmit the Twirla NDA. Even if we do successfully complete the wear study, there is no guarantee that the FDA will find Twirla to have an adequate risk benefit profile or determine that its manufacturing, specifications, and test methods are satisfactory.

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 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. Most recently, the FDA made this same observation with regard to the SECURE trial in its October 2018 FDRR decision. 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

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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. By example, the FDA has consistently expressed concern that the Pearl Index from the SECURE trial is higher than that for any previously approved product.

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 to 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 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 with the clinical trial protocol or fail to 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 to amend a trial protocol;

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

- Clinical study subjects may not follow the study procedures. For instance, in our SECURE study, FDA identified additional on-treatment pregnancies, many of which occurred in women who had delays in applying the patch;

- 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, including comparator drugs, 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.

Furthermore, we plan to rely on a CRO and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the wear study of Twirla and Xulane suggested by FDA, and while we may have agreements governing their committed activities, we have limited influence over their actual performance. Additionally, the CRO and clinical trial sites may have business, regulatory, personnel or other issues that keep us from satisfactorily completing our clinical trials. Any delays or unanticipated problems during clinical trials, such as additional monitoring of clinical trial sites, slower than anticipated enrollment in our clinical trials or subjects dropping out of or being excluded from participation in our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and harm our business. 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. Regulatory approval was further delayed when 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 product performance. We disagreed with the FDA s conclusions regarding the *in vivo* adhesion properties of Twirla and submitted a formal dispute resolution request, or FDRR, to the FDA. In October 2018, the FDA s Office of New Drugs, or OND, formally denied our appeal and provided a path forward for resubmission of the NDA for Twirla that may not require that we reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by DBRUP. Specifically, OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to

Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. We will meet with the FDA regarding the specific design and success criteria of the wear study, which must be successfully completed before we can resubmit the Twirla NDA. Even if we do successfully complete the wear study, there is no guarantee that FDA will find Twirla to have an adequate risk benefit profile or determine that its manufacturing, specifications, and test methods are satisfactory.

In addition, The FDA also indicated in the official minutes of our Type A meeting held in April 2018 and in the October 2018 FDRR decision letter that it anticipates reviewing the safety and efficacy of Twirla during an

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Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The Advisory Committee may recommend non-approval for Twirla or may recommend approval with label restrictions. Even if the Advisory Committee determines that the benefits of Twirla outweigh its risks and recommends approval, the FDA could still 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, and may decline to approve the Twirla NDA or require us to repeat the trial or conduct additional clinical trials prior to obtaining approval.

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, including the wear study of Twirla and Xulane suggested by OND as a path forward for resubmitting the Twirla NDA, may require regulatory submission and 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 without needing to raise additional funds, which we may not be able to do on acceptable terms or at all. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

Our product candidates may have undesirable adverse effects, which may delay or prevent regulatory approval.

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/m2).

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.

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

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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 boxed 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 the 2017 CRL in response to 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. By example, FDA has suggested that we complete a wear study of Twirla s adhesion properties. 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 the 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 we 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 product candidates are in compliance.

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 $3.8 million and $16.0 million for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, we had an accumulated deficit of approximately $237.7 million. We believe that our cash and cash equivalents as of September 30, 2018 will be sufficient to meet our operating requirements into the second quarter of 2019 and will not be sufficient to fund our current and planned operations through the 12 months following the date of this quarterly report on Form 10-Q, which raises substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of our common stock and we may have a more difficult time obtaining financing in the future.

Specialty pharmaceutical product development is a speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. We expect to incur expenses without corresponding revenues until we are able to obtain regulatory approval and subsequently sell Twirla in significant quantities, which may not happen. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We expect we will need to incur additional expenses as we complete the development of Twirla, including the comparative wear study of Twirla and Xulane suggested by the FDA, respond to the 2017

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CRL and seek regulatory approval of Twirla, complete the qualification and validation of our commercial manufacturing process, initiate pre-launch commercial activities, commercially launch Twirla, advance our other potential product candidates and expand our research and development programs. 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 for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting, the resumption and completion of our commercial plan for Twirla, which primarily includes validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates. The timing and cost of the Twirla wear study may affect our ability to fund our operations into the second quarter of 2019. Our planned timeline for seeking approval of Twirla and our ability to fund our operations through the period of time necessary to receive approval of Twirla, if at all, could be adversely affected based on the outcome of our expected meeting with the FDA on the parameters of the wear study, including primarily the scope, size and cost of the study, any or all of which may require us to seek additional funding. 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. To date, we have financed our operations primarily through sales of common stock, convertible preferred stock and convertible promissory notes and to a lesser extent, through term loans and government grants. Our product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

Assuming we obtain FDA approval, and assuming we obtain the additional funding we will require, we expect that our expenses will increase as we prepare for the commercial launch of Twirla. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses may increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise additional capital. We are significantly dependent on the success of Twirla and if we do not obtain FDA approval of Twirla and/or are unable to obtain additional funding, we will need to reassess our operating capital needs and may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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

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

- Successfully complete development of, and receive regulatory approval for Twirla and our other potential product candidates;

- Obtain additional capital for the commercial scale-up of Twirla manufacturing process and commercial launch of Twirla, if approved, as well as advancing the development or our other potential product candidates;

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

- Obtain commercial quantities of our products, if approved, at acceptable cost levels from our third-party manufacturer; and

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

In addition, because of the numerous risks and uncertainties associated with product candidate development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations and resources based on the outcome of our meeting with the FDA about the planned wear study with Twirla and Xulane, or if the results of the comparative wear study of Twirla and Xulane do not support resubmission of our Twirla NDA, and we are required by the FDA or other regulatory authorities to reformulate Twirla, and/or to perform studies or conduct additional work to support regulatory approval in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products.

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

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

In February 2015, we entered into a loan and security agreement, referred to herein as the Hercules Loan Agreement, with Hercules Capital, Inc., or Hercules, for a term loan of up to $25.0 million, or the Term Loan. The Hercules Loan Agreement was amended effective August 25, 2016. 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 term loan with Oxford. Under terms of the Hercules Loan Agreement, we could, but were not obligated to, draw an additional tranche of up to $8.5 million through March 31, 2017, subject to the achievement of certain clinical milestones. 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. The period during which the additional tranche of $8.5 million may be drawn has expired and therefore the $8.5 million can no longer be drawn by us.

The Hercules Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, change our line of business, liquidate or dissolve, enter into any change in control transaction, merge or consolidate with any other entity or acquire all or substantially all the capital stock or property of another entity, incur additional indebtedness, incur certain types of liens on our property, including our intellectual property, pay any dividends or other distributions on our capital stock other than dividends payable solely in capital stock or redeem our capital stock. Our business may be adversely affected by these restrictions on our ability to operate our business.

The Term Loan is secured by substantially all of our property other than our intellectual property. As a result of the amendment to the Hercules Loan Agreement, we were required to make interest-only payments through January 2017. On February 1, 2017, we began making principal payments with respect to the Term Loan. The Term Loan currently bears interest at rate of 9.25% per annum and matures on December 1, 2018.

Additionally, we may be required to repay the outstanding indebtedness under the term loan if an event of default occurs under the Hercules Loan Agreement. Under the Hercules Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the Hercules Loan Agreement or we breach any of our covenants under the Hercules Loan Agreement, subject to specified cure periods with respect to certain breaches; Hercules determines in good faith that we are unable to satisfy our obligations under the Hercules Loan Agreement

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

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

Our operations have consumed substantial amounts of cash since inception. From our inception to September 30, 2018, we have cumulative net cash flows used by operating activities of $208.5 million. We will need to obtain large amounts of additional capital to fund our future operations, including completing the development and commercialization of our product candidates. We will need to obtain additional financing to develop our other potential product candidates, for the approval of our product candidates if requested by regulatory authorities, and to complete the development of any additional product candidates we might acquire Moreover, our fixed expenses such as rent, interest expense and other contractual commitments are substantial and are expected to increase in the future.

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

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

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

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

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

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

- Progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our ongoing, planned and potential future clinical trials;

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

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

- Costs of operating as a public company;

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

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

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- Costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

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

In January 2018, following our receipt of the 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, including commercial pre-launch and manufacturing validation activities, pending our ability to address the 2017 CRL and receive approval of Twirla. In June 2018, we announced a reduction in our workforce, which resulted in the termination of approximately thirty percent of our employees. This workforce reduction, along with other reductions in our planned operating expenses, was designed to reduce operating expenses and preserve cash while we pursued formal dispute resolution, which is now complete. As a result of these planned cost reductions, we believe that our cash and cash equivalents as of September 30, 2018, which were $16.9 million, will be sufficient to meet our projected operating requirements into the second quarter of 2019 which include an estimate of the costs to complete a comparative wear study. The timing and cost of the Twirla wear study may affect our ability to fund our operations into the second quarter of 2019. We will require additional capital to fund operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting, 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. Accordingly, we will be required to obtain further funding through other public or private offerings, debt financing, collaboration or licensing arrangements or other sources.

Our planned timeline for seeking approval of Twirla and our ability to fund our operations through the period of time necessary to receive approval of Twirla, if at all, could be adversely affected based on the outcome of our expected meeting with the FDA on the parameters of the wear study, including primarily the scope, size and cost of the study, any or all of which may require us to seek additional funding. 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. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital when needed or on attractive terms, or we are unable to enter into strategic collaborations, we then may be unable to complete the development of Twirla and may also be required to further cut operating costs, delay, reduce or eliminate our research and development programs or future commercialization efforts or even terminate our operations, which may involve seeking bankruptcy protection.. Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. For instance, 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 have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. If we choose to accelerate elements of our commercial plan or we encounter any unforeseen events that affect our business plan, we may choose to raise additional funds to provide us with additional working capital. Our inability to obtain additional funding when we need it could seriously harm our business and we may be unable to continue our operations at planned levels and be forced to reduce, or even terminate, our operations.

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

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

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

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

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

Risks Relating to the Commercialization of Our Product Candidates

We are significantly dependent on the commercial success of Twirla.

Assuming FDA approval, Twirla will be the first product that we commercialize. The rest of our pipeline of products are in earlier stages of clinical development and will require additional clinical and product development and funding in order to advance towards commercialization, which could take considerable time. If Twirla is not approved, our business, results of operations and ability to advance our pipeline, would be significantly adversely affected. In addition, we will require additional capital for the validation of our commercial manufacturing process and commercial launch of Twirla, if approved. Our ability to generate revenues and become profitable will depend in large part on the commercial success of Twirla. Potential prescribers of Twirla include physicians, nurse practitioners, or NPs, physician s assistants, or PAs, and pharmacists. Registered Pharmacists, or RPh, are authorized to prescribe contraceptives in some states, and other states have pending legislation that would allow pharmacists to prescribe contraceptives. If Twirla or any other product that we commercialize in the future does not gain an adequate level of acceptance among prescribers, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Twirla, and any other product that we commercialize, by prescribers, patients and third-party payors will depend on a number of factors, some of which are beyond our control, including:

- Efficacy, safety and other potential advantages of our product candidates in relation to alternative treatments;

- Relative convenience and ease of administration of our product candidates;

- Availability of adequate coverage or reimbursement of our product candidates by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;

- Prevalence and severity of adverse events associated with our product candidates;
- Cost of our product candidates in relation to alternative treatments, including generic products;
- Extent and strength of our third-party manufacturer and supplier support and ability to meet our market demand;
- Extent and strength of our marketing and distribution support;
- Limitations or warnings contained in our product s FDA approved labeling, including safety warnings and precautions and limitations on the use of Twirla for women based on BMI or weight; and
- Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan.

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

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

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

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

At present, we have no sales personnel and a limited number of marketing personnel. Initially, we do not plan to establish our own sales force, but rather we intend to engage a contract sales organization. Depending on our available capital resources, we plan to hire a limited number of additional marketing personnel and engage a contract sales organization in the United States shortly after the FDA approval of Twirla. At the time of our anticipated commercial launch of Twirla, assuming regulatory approval by the FDA, our sales and marketing team will have worked together for only a limited period of time. If our regulatory review period by the FDA for our

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NDA resubmission is extended beyond six months, we may need to further delay initiating certain commercial activities in order to preserve cash, in which case our ability to launch Twirla would be compromised. We cannot guarantee that we will be successful in marketing Twirla in the United States.

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

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

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

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

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

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

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

- Differing regulatory requirements in foreign countries including, among others, requirements relating to drug approvals, reimbursement and sales and marketing practices;

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

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

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

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

Risks related to the contraceptive market landscape include:

- The prescription contraceptive market could experience a decrease in growth or negative growth if fewer women choose to use hormonal contraception;

- The perceived safety of hormonal contraceptives could be negatively affected by media reports of adverse effects and advertisements for mass tort lawsuits due to adverse effects;

- Price pressures from third party payors, including managed care organizations and government-sponsored health systems, could limit our revenue;

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

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

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

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- Healthcare reform activities, including, without limitation, the repeal, reform or replacement of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 or, collectively, the Affordable Care Act, or ACA, and its effect on pharmaceutical coverage, reimbursement and pricing could limit our revenue;

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

- Our ability to access pharmacists in states where they are authorized by law to prescribe contraceptives could be limited, decreasing our ability to promote Twirla.

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

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

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

- Limitations on use or warnings contained in FDA-approved labeling, which could include, for example, limitations on the use of Twirla for women based on BMI or weight;

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

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

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

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

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

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

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

Moreover, we may face additional generic or other drug product competition sooner than we anticipate for Twirla or our other potential product candidates, which would potentially limit their commercial success. We believe that we may be eligible for three years of FDA marketing exclusivity for Twirla and our other potential product candidates. The FDCA provides a period of three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA for a drug product that contains a previously approved active moiety, if new clinical investigations, other than bioavailability or bioequivalence studies, were conducted or sponsored by the applicant and are determined by the FDA to be essential to the approval of the application. This

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three-year marketing exclusivity, however, does not protect drug products from all competition. For instance, it does not protect against the approval of a full NDA. It also would only protect against the approval of a product that contains the same conditions of approval as our product candidates. We may not receive the three-year exclusivity for any of our product candidates, and, even if we do, it may not adequately protect us from competition. Competition that our product candidates may face from generic or similar versions of our product candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

If Twirla is approved, but does not achieve an adequate level of acceptance by prescribers, third-party payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate prescribers, patients and third-party payors on the benefits of Twirla may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors and become profitable, if the market for hormonal contraceptives fails to achieve expected future growth or decreases, we may not generate sufficient revenue or sustain profitability. Our ability to generate sufficient revenue from Twirla will also be dependent on our ability to support the commercial demand for Twirla and we cannot assure you that we along with our manufacturing partner Corium will be able to complete validation of our commercial manufacturing successfully and in a timely manner, and, ultimately, adequately meet the commercial demand for Twirla, if approved.

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

The proportion of the U.S. market that is made up of generic products has been increasing over time. In 2005, generic contraceptive products held 47% of prescription volume and 34% of sales and, by 2011, those values had risen to 68% and 44%, respectively. For the year ended December 31, 2017, approximately 85% of the prescription volume and approximately 50% of sales of combined hormonal contraceptives, or CHCs, in the U.S. were generated by generic products. Recently, Congress and the FDA have taken steps to increase generic competition in the market. If this trend continues, it may be more difficult to introduce Twirla, if approved, as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Twirla in order to overcome the trend towards generics and to gain access to reimbursement by payors. If we are unable to introduce Twirla at a price that is commensurate with that of current branded contraceptive products, or we are unable to gain reimbursement from payors for Twirla, or if patients are unwilling to pay any price differential between Twirla and a generic contraceptive, our revenues will be limited. For example, in light of the introduction of the generic version of the Ortho Evra product by Mylan Inc. in April 2014, and the subsequent discontinuation of distribution of Ortho Evra in October 2014 by Janssen, in order to be competitive and gain market share, we may increase the rebates available to commercial payors or we may provide incentives to consumers covered by non-governmental payors, such as coupons or rebates, in order to make up for the difference in the co-payment for Twirla and the generic patch product.

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

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

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

- Following the approval of Evra, the manufacturer of Evra and the FDA began receiving reports of thrombotic and thromboembolic events.

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

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by measuring the amount of time it takes for the drug to be absorbed, distributed and eliminated throughout the body.

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

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

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

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

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

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

We have conducted pharmacokinetic studies of Twirla to demonstrate that it delivers a daily EE dose of approximately 30 micrograms, comparable to a low-dose oral contraceptive. However, because none of our completed or planned clinical trials studied or expect to study Twirla in a head-to-head comparison with Evra, if Twirla is approved by the FDA, we will not be able to make direct comparative claims regarding the safety and efficacy of Twirla as compared to Evra. While we expect Twirla, if approved, to have the same boxed warning currently required for all CHCs, we cannot predict whether the FDA will require that we include information in the Twirla labeling or boxed warning regarding the additional risks associated with the Evra patch. Assuming approval, if we are not able to convince prescribers, patients and payors that Twirla delivers a low daily dose of EE, this may limit uptake and usage of Twirla and our revenue will be limited.

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

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

Our potential competitors include large, well-established pharmaceutical companies, and specialty pharmaceutical sales and marketing companies. These companies include Merck & Co., Inc., or Merck, which markets Nuvaring®, TherapeuticsMD, which has licensed and will market Annovera®, a recently approved contraceptive ring, Allergan, Inc., or Allergan, which markets several branded and generic contraceptives including Minastrin® 24, LoLoestrin®, and Taytulla®, Bayer AG, or Bayer, which markets Beyaz®, Yaz®, Yasmin®, and Natazia®, and Mylan N.V., which markets Xulane®, a generic version of Ortho Evra. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives, including Sandoz

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International GmbH, Glenmark Pharmaceuticals Ltd., Lupin Pharmaceuticals, Inc., and Amneal Pharmaceuticals, Inc.

There are other contraceptive product candidates in development that, if approved, would potentially compete with Twirla. Specifically, Bayer has a contraceptive patch approved in the European Union, or E.U. Bayer entered into a license and distribution agreement for the sale of this contraceptive patch in Europe with Gedeon Richter Ltd. Other companies that have new contraceptive product candidates in various stages of development include Allergan (vaginal ring in Phase 3) and Antares Pharma, Inc. (transdermal gel contraceptive in Phase 2).

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

The network through which we will sell our products, if and when approved, has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large distributors control a significant share of the market. In 2012, three companies generated about 85% of all revenues from drug distribution in the United States, and in 2010, four chain pharmacy companies owned about 30% of all retail pharmacy outlets. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

Existing and future legislation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize Twirla and our other potential product candidates and may affect the prices we may obtain.

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

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

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

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

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reasonable medical management techniques, such as the application of cost-sharing obligations. An amendment was issued that provided an exemption to the contraceptive mandate for group health plans established or maintained by religious employers. However, the contraceptive mandate has remained controversial, with several legal challenges filed around the country. In June 2014, the U.S. Supreme Court ruled that owners of certain private companies can object to the contraceptive mandate on religious grounds and in November 2015, the Court agreed to hear arguments from non-profit organizations requesting similar treatment. In October 2017, the U.S. Department of Health and Human Services announced it will seek to issue regulations that will allow all companies to qualify for the exemption from the contraceptive mandate on the basis of religious and moral grounds. Although it is too early to determine the full effect of the contraceptive mandate and other provisions of the ACA on our business, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, the U.S. Congress is potentially pursuing legislation, which, if passed and signed into law by the current administration, would repeal and possibly replace certain aspects of the ACA. Further, on January 20, 2017, the current administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices among others. There are several proposals to reform the federal healthcare laws being advocated and it is still unclear whether such reform efforts will succeed and if so, which proposals will ultimately be successful. Therefore, it is difficult to determine the full effect of the ACA or any other healthcare reform efforts on our business. Any replacement, however, would likely provide less aggregate health care coverage.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of our product candidates and reduce our profitability.

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

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

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

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

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

Risks Related to Manufacturing and Our Reliance on Third Parties

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

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

As a third-party manufacturer, Corium s business operations are completely beyond our control and we have no influence over whether Corium is acquired, merges with another company, changes its management or its business operations, or discontinues them entirely. For example, on October 11, 2018, Corium announced that it has entered into a definitive merger agreement under which Gurnet Holding Company, or GHC, will acquire Corium. Following completion of the transaction, Corium will become a private company, wholly owned by GHC. Corium announced that it plans to continue its operations in Grand Rapids, Michigan, where Twirla is expected to be commercially manufactured, if approved, and where clinical Twirla supply is manufactured. While we currently have no indication that the merger will impact the manufacture of Twirla, we cannot guarantee that the merger will not disrupt the manufacture of Twirla, that contract manufacturing will remain part of Corium s business model, or that as a result of the merger, there will not be other unforeseen changes that could materially affect the manufacture of Twirla.

Furthermore, we do not control the manufacturing process of Twirla, and are completely dependent on Corium for compliance with the FDA s manufacturing regulatory requirements for manufacture of Twirla, our other potential product candidates and our products, if and when approved. If Corium or other contract manufacturers that we may use cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. The facilities used by Corium to manufacture our product candidates must be approved by the FDA pursuant to inspections that are conducted in connection with the FDA s review of our NDA for Twirla. On December 21, 2017, the FDA issued the 2017 CRL, indicating that our resubmitted NDA for Twirla 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 observations identified during a PAI for the Twirla NDA of Corium s facility must be resolved. In November 2017 and December 2017, Corium provided the FDA with responses to each of the observations made during the FDA s facility inspection, which included a PAI for Twirla which we do not know whether the FDA will find acceptable.

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In addition, while Corium has provided the FDA with responses to each of the observations made during the FDA s facility inspection, the sufficiency of these responses, as well as our responses concerning the quality control adhesion test methods and specifications, will be evaluated by the FDA after we resubmit the NDA for Twirla. 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 may determine that our responses to the manufacturing deficiencies in the 2017 CRL and Corium s responses to the past or future 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 basis as well. For example, the FDA could determine that we and Corium have not established comparability between the manufacturing process used in producing the clinical supplies for our SECURE clinical trial and the manufacturing process Corium plans to use to produce commercial supplies of Twirla, if approved, or that we or Corium have not adequately addressed the FDA s 2017 CRL and PAI comments and findings, which in turn could require us and Corium to perform additional work, incur significant costs and delay the timeline for the resubmission of our NDA. 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 during past or future inspections, the FDA may deny approval of Twirla or 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.

In the official minutes of the Type A meeting we had with the FDA in April 2018, the FDA also provided guidance on the path forward for addressing the manufacturing quality control test method issues related to Twirla and informed us that whether these issues have been adequately addressed would be subject to review by the FDA when we resubmit our Twirla NDA. There can be no assurance we or Corium will address the outstanding FDA questions in a manner sufficient for approval in the United States.

In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities that would also require FDA approval, and which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, if our contract manufacturer cannot successfully manufacture materials that conform to our specifications and the strict regulatory requirements of the FDA, we may be subject to other regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of product or investigational approvals, clinical holds or termination of clinical trials, refusals to approve pending applications, disgorgement, restitution, exclusion from federal healthcare programs product seizures and detention, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution. If our contract manufacturer experiences issues in its manufacturing process or is unable to produce clinical supplies in adequate quantity and quality, our clinical trials, including our comparative wear study, could be delayed, or the results of the comparative wear study could be negatively affected, or our ability to receive regulatory approval of our product candidates could be negatively affected. Additionally, if there are changes to the manufacturing process for Twirla or to our formulation for Twirla that require a change in the manufacturing process, we could experience significant additional cost and our ability to receive regulatory approval could be delayed.

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

which could delay, prevent, or impair the commercialization of Twirla, if approved, and the development of our other potential product candidates.

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

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

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

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

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

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

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

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

- The disruption and costs associated with changing suppliers.

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

Our third-party manufacturer is subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. In addition to the above-described regulatory actions, failures by our third-party manufacturer to comply

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with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another third-party manufacturer that meets all regulatory requirements.

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

We, through our manufacturing partner Corium, rely on a number of third parties for the supply of active ingredients, other raw materials and laboratory services for the supply of our product candidates and, assuming FDA approval, commercialization of Twirla. Our ability to develop our product candidates depends, in part, on Corium s ability to successfully obtain the active pharmaceutical ingredients used in our product candidates, in accordance with regulatory requirements and in sufficient quantities for clinical testing and later commercialization. If Corium fails to develop and maintain supply relationships with these third parties, we may be unable to continue to develop our product candidates or commercialize any approved products in the future. Moreover, these third parties will be subject to FDA inspection. If these third parties do not comply with the FDA s regulatory requirements, we may not be able to receive or maintain approval for Twirla or any of our other product candidates, and we may be subject to other regulatory enforcement action such as adverse inspectional findings, Warning Letters, Untitled Letters, recall requests, withdrawal of investigational approvals, clinical holds, or termination of clinical trials, refusals to approve pending applications, disgorgement, restitution, exclusion from federal healthcare programs, product seizures and detention, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, refusal to permit import or export of the product and injunction against or restriction of manufacture or distribution.

We, through Corium, also rely on certain third parties as the current sole source of the materials they supply. Although many of these materials are produced in more than one location or are available from another supplier, if any of these materials becomes unavailable to us for any reason, we likely would incur added costs and delays in identifying or qualifying replacement materials and there can be no assurance that replacements would be available to us on acceptable terms, or at all. In certain cases, we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay development of our product candidates and, assuming FDA approval, commercial production of Twirla, indefinitely. For example, the sole manufacturer of one of the components of the packaging of our Twirla patch notified us that it would be discontinuing manufacture of the component. We currently believe that manufacturing of this component has now been discontinued. In conjunction with Corium, we were able to secure an amount of inventory of the packaging component that we believe will last until at least 2021. We are currently evaluating sources for a replacement for this discontinued component and, assuming FDA approval of this replacement material, we could eventually use the replacement material in connection with the commercial production of Twirla.

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

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

Corium s facilities used for the manufacture of our product candidates must be maintained in a manner compliant with the FDA s manufacturing requirements, including obtaining favorable inspection reports. We do not control the manufacturing process and are dependent on Corium for compliance with the FDA s requirements for manufacture of Twirla and our other potential product candidates. If Corium cannot successfully manufacture material components and finished products that conform to our specifications and the FDA s strict regulatory requirements, they and we may be subject to regulatory action, including adverse inspectional findings, Warning Letters, Untitled Letters, product recall requests, withdrawal of product or investigational approvals, non-approval of

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marketing applications, clinical holds or termination of clinical trials, disgorgement, restitution, exclusion from federal healthcare programs, detentions or seizures, refusal to allow the import or export of a product, injunction against or restriction of manufacture or distribution, consent decrees, corporate integrity agreements, criminal and civil penalties, including imprisonment, and Corium may not be able to maintain FDA approval for its manufacturing facilities or acceptance of its manufacturing data in regulatory filings. For example, the 2017 CRL identifies deficiencies relating to quality control adhesion test methods and specifications which are part of the manufacturing process for Twirla and also noted that objectionable conditions identified during an inspection of Corium must be resolved, among other deficiencies further discussed in our Annual Report on Form 10-K, which we filed with the SEC on March 12, 2018. If Corium s facilities cannot maintain compliance with FDA requirements, we may need to find and successfully qualify alternative manufacturing facilities, which could result in supply interruptions of Twirla and our other potential product candidates and substantial additional costs as a result of such delays, including costs with respect to finding alternative manufacturing facilities, and lost revenues. There is further no guarantee that the FDA would approve these alternative facilities.

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

We currently rely and plan to continue to rely on CROs and clinical trial sites for most aspects of our clinical trials, such as trial conduct, data management, statistical analysis and electronic compilation of our NDA. We have entered into an agreement with a CRO to conduct the planned comparative wear study of Twirla and Xulane. We may enter into agreements with additional CROs and clinical trial sites to obtain additional resources and expertise in an attempt to accelerate our progress with regard to new or ongoing clinical and preclinical programs. Entering into relationships with CROs and clinical trial sites involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and clinical trial sites and the time the CRO and sites commences work. As a result, delays may occur, which may materially impact our ability to meet our desired clinical development timelines and ultimately have a material adverse impact on our operating results, financial condition or future prospects.

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

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imprisonment, injunction against manufacture or distribution and debarment. As a result, our financial results and the commercial prospects for our product candidates would be harmed and our costs would increase.

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

We may seek partnerships, collaborations and other strategic transactions to maximize the commercial potential of Twirla, our other potential product candidates and our proprietary technologies in the United States and territories throughout the world. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for Twirla and each of our other product candidates and technologies, both in the United States and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex, and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Collaborators, also, may not comply with the applicable regulatory requirements, which may subject them or us to enforcement actions.

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

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

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

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

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Risks Related to Regulatory Matters Following Approval

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

Even if we obtain U.S. regulatory approval of Twirla or other potential product candidates, the FDA may still impose significant restrictions on their indicated uses, including more limited patient populations, require that precautions, contraindications, or warnings be included on the product labeling, including boxed warnings, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Claims that we may make may also be restricted through our approved labeling. For example, based on the SECURE clinical trial 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. 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 30 kg/m2). The October 2018 FDRR decision letter did not reach a decision on efficacy. Nonetheless, OND did communicate that upon its initial review, our analyses of population differences and study design do not seem to support our conclusions regarding efficacy results from SECURE. However, 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. A fuller assessment of the clinical outcomes from the SECURE trial, and specifically the safety and efficacy of Twirla, will need to be conducted by the FDA and a likely Advisory Committee when or if we resubmit our NDA for Twirla.

The FDA indicated in the official minutes of our April 2018 end of review Type A Meeting and in the October 2018 FDRR decision letter that it anticipates reviewing the safety and efficacy of Twirla, including the Pearl Index that the FDA noted is substantially higher than other previously approved combined hormonal contraceptives, during an Advisory Committee meeting to obtain input on whether the benefits outweigh the risks. The Advisory Committee may recommend non-approval for Twirla or may recommend approval with label restrictions. Even if the Advisory Committee determines that the benefits of Twirla outweigh its risks and recommends approval, the FDA could still 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. As such, we may not obtain approval of Twirla based on these data or any other basis. Even if we receive approval of Twirla, 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 or otherwise require labeling limitations or warnings for such subpopulation, which could limit the commercial potential of the product, if approved. The FDA may further require us to include other information and/or data in the label for Twirla that may make it more difficult for us to successfully commercialize the product, if approved. For instance, the FDA may require us to include the Pearl Index results from the previously conducted Phase 3 trials, which were higher than the SECURE clinical trial s overall and certain sub-group Pearl Index results. We will discuss specific labeling requirements with the FDA in the future.

If approved, Twirla and our other potential product candidates, if approved, will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development. These requirements include registration with the FDA, listing of our drug products, payment of annual fees, as well as continued compliance with cGCPs for any clinical trials that we conduct post-approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA s manufacturing requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we are found to be noncompliant with applicable requirements, the FDA and other government authorities may issue a Warning Letter or Untitled Letter, or take other

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regulatory action such as a product seizure and detention, withdrawal of product approval, request for a recall, refusal to allow the import or export of the product, criminal or civil penalties, injunction against or restriction of manufacture or distribution, consent decrees, disgorgement, restitution, clinical holds or terminations of clinical trials, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

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

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

In addition, if Twirla and our other potential product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services Office of Inspector General, state attorneys general, members of Congress and the public. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling, a practice known as off-label promotion. If we receive marketing approval for Twirla or our other potential product candidates, physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. For example, we believe that Twirla, if approved, will have labeling consistent with other marketed hormonal contraceptive products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clots, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease, and hypertension, and a boxed warning regarding risks of smoking and CHC use, particularly in women over 35 years old that smoke. However, regulatory authorities may require the inclusion of additional statements about adverse events in the label, including additional boxed warnings or contraindications, as well as additional labeled limitations, such as limitations on the use of Twirla for women based on BMI or weight.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-

label drug uses involving fines that are as much as $3.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

- Issuance of Warning Letters, Cyber Letters or Untitled Letters;

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

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

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

- Clinical holds or termination of clinical trials;

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

- Suspension or withdrawal of regulatory approval;

- Suspension of any ongoing clinical trials;

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

- Debarment;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

Risks Related to Intellectual Property Rights

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

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee s ability to maintain our patents and to obtain additional patent protection in the United States and other countries with respect to our proprietary technology and products. We believe we will be able to obtain, through prosecution of our pending patent applications, additional patent protection for our proprietary technology. If we are compelled to spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer for sale the same or similar products containing the generically available active pharmaceutical ingredients in our product candidates, which could materially adversely affect our competitive business position and harm our business prospects. Our patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our product candidates. Even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

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

- The active pharmaceutical ingredients in our product candidates are generic and therefore our patents do not include claims directed solely to the active pharmaceutical ingredients;

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- Our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates using the same active pharmaceutical ingredients;

- There can be no assurance that the term of patent protection will be long enough for our company to realize sufficient economic value under the patents following commercialization of our product candidates;

- We do not expect, upon approval of our NDA, to receive patent term restoration under the Hatch-Waxman Act for the patents that have been, or will be, submitted to the FDA for listing in the Orange Book;

- Our issued patents and pending patent applications that may issue as patents in the future may not prevent entry into the U.S. market or other markets of generic versions of our Twirla and AG890 product candidates;

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

- We do not at this time own or control issued foreign patents in all markets that would prevent generic entry into some markets for our product candidates;

- We may be required to disclaim part of the term of one or more patents;

- There may be prior art of which we are not aware that may affect the validity or enforceability of one or more patent claims;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement or misappropriation. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a

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successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our product candidates or their use, the holders of any of these patents may be able to block our ability to commercialize our product candidates unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product candidates or lead to prohibition of the manufacture or sale of product candidates by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information, know-how or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Many of our employees, consultants and contractors were previously employed at or engaged by biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any threatened or pending claims related to these matters or concerning agreements with our senior management, or other of our employees, consultants and contractors, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

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

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

In addition, our patents and patent applications in the United States and other jurisdiction could face other challenges, such as derivation or interference proceedings, opposition proceedings, *inter partes* review, reexamination proceedings, third party submissions of prior art, and other forms of post-grant challenges. In the United States, for example, post-grant review, which is similar to opposition proceedings available in many countries other than the U.S., was newly established by the Leahy-Smith Act. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel s time and attention.

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

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

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

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Risks Related to the Development of Our Additional Potential Product Candidates

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

A key element of our long-term strategy is to develop, obtain regulatory approval for and commercialize our portfolio of potential product candidates in addition to Twirla. To do so, we plan to utilize our proprietary transdermal delivery technology, Skinfusion®, to develop additional potential product candidates. We may not be successful in our efforts to develop our portfolio of additional potential product candidates, and any product candidates we do develop may not produce commercially viable products that safely and effectively treat their indicated conditions. To date, our efforts have identified three additional potential product candidates in addition to Twirla, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle, AG200-SP, which is a regimen designed to provide shorter, lighter periods, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-SP and AG200-ER are intended to be Twirla line extensions that would expand the use of Twirla beyond its initial approved use. In July 2016, we began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the woman s cycle. We have decided to postpone the trial and will continue to evaluate the timing for initiating dosing of subjects for this Phase 2 clinical trial, which is dependent on financial and other capital resources. Our planned Phase 2 clinical trial of AG200-SP (SmP) is only the initial clinical trial in this program and AG200-SP (SmP) will require additional clinical trials to establish the safety and efficacy of this product candidate. The other potential product candidates in our pipeline will require additional product development efforts to optimize patch formulations and dosing. In addition, we will need to conduct additional clinical trials to establish the safety and efficacy of these potential product candidates, which will require additional capital. We would be unable to develop these potential product candidates, in particular AG200-SP and AG200-ER, if we are unable to get Twirla approved. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla, which will now include designing and implementing the comparative wear study of Twirla and Xulane suggested by the FDA. We will require additional capital to resume and complete the commercialization plan for Twirla, if approved, and to advance the development of our other potential product candidates.

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

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

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

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

- We may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on our investment in such product;

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- Companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us;

- We may be unable to identify suitable products or product candidates within our areas of expertise; or

- We may not have sufficient funds to acquire, develop or commercialize additional product candidates or technologies.

Risks Related to Our Business Operations and Industry

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

As of September 30, 2018, we had a total of 13 full-time employees after a reduction in our workforce, which resulted in the elimination of the positions of several employees primarily from our commercial and clinical teams, representing approximately thirty percent of our employees. We use third-party consultants to assist with our current, limited sales and marketing functions. As our development and commercialization plans and strategies develop, we expect to need to expand the size of our employee base for managerial, operational, commercial, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Twirla, if approved, and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided these employees with stock options that vest over time. In June 2018, we announced a reduction in our workforce, which resulted in the termination of approximately thirty percent of our employees. On June 20, 2018, after the reduction in workforce, we adopted a retention plan that provides all of our remaining employees (i) future cash retention payments to induce such employees to remain employed by us through December 31, 2018 and (ii) stock option grants that vest over time in four equal installments to induce such employees to remain employed by us through December 31, 2019. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

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

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more

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diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can develop and commercialize product candidates would be limited.

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

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

- Decreased demand for Twirla or any future product candidates that we may develop;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Costs to defend any related litigation;
- A diversion of management s time and our resources;
- Substantial monetary awards to trial participants or patients;
- Product recalls, withdrawals or labeling, marketing or promotional restrictions;
- Regulatory authority withdrawal of product approvals or refusal to approve pending applications;

- Loss of revenue;
- The inability to commercialize Twirla or our other potential product candidates, if approved;
- A decline in our stock price; and
- Exposure to adverse publicity.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a $10.0 million annual aggregate coverage limit. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

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

Our business is affected by macroeconomic conditions.

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

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

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

As a public company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. We estimate that we will annually incur approximately $2.0 million in expenses in response to these requirements.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the SEC. However, for as long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

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

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code of 1986, as amended, and may be subject to further limitation as a result of our initial public offering.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax-exempt rate and the value of the company s stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability. Our net operating loss carryforwards arising in taxable years ending on or prior to December 31, 2017 will expire between 2018 and 2037 if we have not used them. Net operating loss carryforwards arising in taxable years ending after December 31, 2017 are no longer subject to expiration under the Code.

In addition, it is possible that the transactions relating to our initial public offering or subsequent public offerings, either on a standalone basis or when combined with future transactions, have caused us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 of the Code. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception.

Risks Related to Ownership of Our Common Stock

We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Global Market, our common stock could be delisted, which could affect our common stock s market price and liquidity and reduce our ability to raise capital.

On July 2, 2018, we received a letter from The Nasdaq Stock Market LLC, or Nasdaq, indicating that we have failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1). Nasdaq Listing Rule 5450(a)(1) requires that companies listed on the Nasdaq Global Market maintain a minimum closing bid price of at least $1.00 per share. The notification of noncompliance had no immediate effect on the listing or trading of our common stock, which continues to trade on the Nasdaq Global Market under the symbol AGRX .

Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180-calendar day grace period, or until December 31, 2018, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if our common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period.

If we are not in compliance by December 31, 2018, we may be afforded a second 180 calendar day period to regain compliance in connection with a transfer to The Nasdaq Capital Market. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary. Nasdaq could refuse to provide the additional 180 calendar day period if it does not appear to Nasdaq that it is possible for us to cure the deficiency.

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If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. At that time, we may appeal the Nasdaq Staff s determination to a Hearings Panel.

We intend to monitor the closing bid price of our common stock and consider our available options to resolve the noncompliance with the minimum bid price requirement. No determination regarding our response has been made at this time. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria. If our securities are delisted, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

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

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

We expect that our stock price may fluctuate significantly.

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

- Our ability to successfully complete the comparative wear trial of Twirla and Xulane suggested by the FDA and obtain results that support resubmission our Twirla NDA;

- Any delay in filing our response to the 2017 CRL received from the FDA with respect to Twirla and any adverse development or perceived adverse development with respect to the FDA s review of our response;

- Our failure to receive approval of Twirla;

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

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

- Regulatory actions with respect to Twirla;

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

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

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

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

- Actual or anticipated changes in our growth rate relative to our competitors;
- Competition from existing products or new products that may emerge;
- Announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- Issuance of new or updated research or reports by securities analysts;
- Fluctuations in the valuation of companies perceived by investors to be comparable to us;
- Share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- Additions or departures of key management or scientific personnel;
- Disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Announcement or expectation of additional debt or equity financing efforts;
- Sales of our common stock by us, our insiders or our other stockholders; and
- General economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the Nasdaq Global Market and the stock prices of pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

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

If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

As of November 1, 2018, we had 34,377,329 shares of common stock outstanding. Of these shares, 33,953,593 shares of common stock are freely tradeable, without restriction, in the public market. Moreover, a relatively small number of our stockholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

In addition, the 5,835,455 shares subject to outstanding options and restricted stock units under our stock option plans and the 1,988,069 shares reserved for future issuance under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations.

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

Our market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation. Litigation of this type could result in substantial costs and diversion of management s attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities. On January 6, 2017, and January 20, 2017, two previously disclosed complaints captioned *Peng v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner* , No. 17-cv-119 (D.N.J.), and *Lichtenthal v. Agile Therapeutics, Inc., Alfred Altomari, and Elizabeth Garner* , No. 17-cv-405 (D.N.J.), respectively, were filed in the United States District Court for the District of New Jersey on behalf of a putative class of investors who purchased shares of our common stock from March 9, 2016, through January 3, 2017. The complaints alleged violations of the federal securities laws based on public statements made regarding our Phase 3 SECURE clinical trial and sought an unspecified amount of damages to be determined at trial. We denied all allegations in the complaints. On May 15, 2017, the complaints were consolidated as *In re Agile Therapeutics, Inc. Securities Litigation*, Master File No. 17-cv-119 (D.N.J.), and Hoyt W. Clark was appointed as class representative for the putative class. On June 26, 2017, Mr. Clark agreed to dismiss the case voluntarily, without payment by us of any consideration and with each side bearing its own attorneys fees and costs. The presiding judge dismissed the consolidated action with prejudice as to all defendants on July 13, 2017.

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

As of September 30, 2018, our executive officers, directors, director nominees, holders of 5% or more of our capital stock and their respective affiliates together beneficially owned approximately 40.3% of our outstanding voting stock.

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

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

We will have considerable discretion in the application of the net proceeds from our completed public offerings. We intend to use the majority of the net proceeds from our completed public offerings to obtain marketing approval for Twirla, begin preparations for the U.S. commercial launch of Twirla, complete the equipment qualification and validation related to the expansion of Corium s manufacturing capabilities in preparation for potential commercial operations, develop our product pipeline, and for working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, validation of capital equipment and the costs of operating as a public company. As a result, investors will be relying upon management s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds from our recently completed private placement and public offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from our recently completed public offerings in a manner that does not produce income or that loses value.

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

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender

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offer or proxy contest involving our company. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	**Description of Document**
31.1	Certification of the Registrant s Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Registrant s Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Registrant s Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of the Registrant s Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Stockholders Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.

* The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 2, 2018	Agile Therapeutics, Inc.	
	By:	/s/ Alfred Altomari Alfred Altomari President and Chief Executive Officer (Principal Executive Officer)
Date: November 2, 2018		
	By:	/s/ Scott M. Coiante Scott M. Coiante Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)