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,		Nine Months Ended September 30,	
	2018	2017	2018	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.

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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

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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.

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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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Agile Therapeutics, Inc.

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(in thousands, except share and per share data)

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,		Nine Months Ended September 30,	
	2018	2017	2018	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,		Nine months ended September 30,	
	(In thousands)			
	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 act