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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2019

OR

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

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	**Trading Symbol**	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

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

There were 44,775,811 shares of the registrant's common stock, $0.0001 par value, outstanding as of July 31, 2019.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2019

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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 variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Quarterly Report on 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 Quarterly Report on 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 Quarterly Report on 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 Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

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

- our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern;
- the potential that the U.S. Food and Drug Administration, or FDA determines that our data does not support approval of the Twirla new drug application, or NDA, and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the second Twirla complete response letter, or 2017 CRL;
- our ability to obtain a favorable advisory committee vote regarding the benefit and risk profile of Twirla, which is currently planned for October 30, 2019;
- our ability to obtain and maintain regulatory approval of the Twirla NDA and our product candidates, and the labeling under any approval we may obtain;
- our ability to attract and retain key employees;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

- our third-party manufacturer, Corium International, Inc.'s, or Corium, inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA;
- our ability along with Corium to pass an FDA pre-approval inspection, or PAI, and complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer;
- the success and timing of our clinical trials or other studies;
- our ability along with our study investigators to pass any FDA inspections of our clinical sites;
- regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown;
- our plans to commercialize Twirla and develop our other potential 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 or other tests and studies; and
- our ability to successfully implement our business strategy.

Any forward-looking statements that we make in this Quarterly Report on 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 Quarterly Report on Form 10-Q. You should also read carefully the factors described in the "Risk Factors" included in Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the Securities and Exchange Commission on March 12, 2019 to better understand significant 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 Quarterly Report on 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 Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

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

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

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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 10,586	$ 7,851
Prepaid expenses	178	607
Total current assets	10,764	8,458
Property and equipment, net	13,906	13,916
Right of use and other assets	250	18
Total assets	$ 24,920	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 804	$ 875
Accrued expenses	803	1,343
Lease liability, current portion	167	—
Total current liabilities	1,774	2,218
Lease liability, long-term	82	—
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 44,632,329 and 34,377,329 issued and outstanding at June 30, 2019 and December 31, 2018, respectively	4	3
Additional paid-in capital	272,977	261,722
Accumulated deficit	(249,917)	(241,551)
Total stockholders' equity	23,064	20,174
Total liabilities and stockholders' equity	$ 24,920	$ 22,392

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Operations
(Unaudited)
(in thousands, except par value and share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 1,779	$ 2,413	$ 4,660	$ 6,372
General and administrative	1,768	2,318	3,594	5,404
Restructuring costs	—	416	—	416
Total operating expenses	3,547	5,147	8,254	12,192
Loss from operations	(3,547)	(5,147)	(8,254)	(12,192)
Other income (expense)				
Interest income	63	101	101	198
Interest expense	—	(320)	—	(689)
Change in fair value of warrants	—	22	—	29
Total other income (expense), net	63	(197)	101	(462)
Loss before benefit from income taxes	(3,484)	(5,344)	(8,153)	(12,654)
Benefit from income taxes	—	—	—	477
Net loss	$ (3,484)	$ (5,344)	$ (8,153)	$ (12,177)
Net loss per share (basic and diluted)	$ (0.08)	$ (0.16)	$ (0.20)	$ (0.36)
Weighted-average common shares (basic and diluted)	43,776,549	34,277,601	40,560,259	34,253,515

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Changes in Stockholders' Equity
(Unaudited)
(in thousands, except par value and share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount			
Six Month Period Ended June 30, 2019					
Balance December 31, 2018	34,377,329	$ 3	$ 261,722	$ (241,551)	$ 20,174
Adjustment to derivitive liabilities upon adoption of ASU 2017-11	—	—	213	(213)	—
Share-based compensation - stock options and RSUs	—	—	490	—	490
Issuance of common stock in private placement, net of expenses	8,426,750	1	7,809	—	7,810
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	665,974	—	860	—	860
Vesting of RSUs	145,204	—	—	—	—
Net loss	—	—	—	(4,669)	(4,669)
Balance March 31, 2019	43,615,257	$ 4	$ 271,094	$ (246,433)	$ 24,665
Share-based compensation - stock options	—	—	479	—	479
Issuance of common stock pursuant to at-the-market stock sales, net of expenses	992,072	—	1,389	—	1,389
Issuance of common stock upon exercise of stock options	25,000	—	15	—	15
Net loss	—	—	—	(3,484)	(3,484)
Balance June 30, 2019	44,632,329	$ 4	$ 272,977	$ (249,917)	$ 23,064
Six Month Period Ended June 30, 2018					
Balance December 31, 2017	34,186,342	$ 3	$ 258,092	$ (221,772)	$ 36,323
Share-based compensation - stock options and RSUs	—	—	1,119	—	1,119
Vesting of RSUs	61,926	—	—	—	—
Net loss	—	—	—	(6,833)	(6,833)
Balance March 31, 2018	34,248,268	$ 3	$ 259,211	$ (228,605)	$ 30,609
Share-based compensation - stock options and RSUs	—	—	988	—	988
Vesting of RSUs	129,061	—	—	—	—
Net loss	—	—	—	(5,344)	(5,344)
Balance June 30, 2018	34,377,329	$ 3	$ 260,199	$ (233,949)	$ 26,253

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (8,153)	$ (12,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	12
Amortization	71	—
Noncash stock based compensation	969	2,106
Noncash interest	—	262
Change in fair value of warrants	—	(29)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	429	562
Accounts payable and accrued expenses	(590)	(644)
Lease liability	(75)	—
Net cash used in operating activities	(7,339)	(9,908)
Cash flows from investing activities:		
Acquisition of property and equipment	—	(316)
Net cash used in investing activities	—	(316)
Cash flows from financing activities:		
Proceeds from issuance of common stock in private placement, net of offering costs	7,810	
Proceeds from At-the-Market sales of common stock, net of offering costs	2,249	
Principal payments of loan payable	—	(3,263)
Proceeds from exercise of stock options	15	—
Net cash provided by (used in) financing activities	10,074	(3,263)
Net increase (decrease) in cash and cash equivalents	2,735	(13,487)
Cash and cash equivalents, beginning of period	7,851	35,952
Cash and cash equivalents, end of period	$ 10,586	$ 22,465
Supplemental disclosure of noncash financing activities		
Supplemental cash flow information		
Interest paid	$ —	$ 449
Cash paid for income taxes	$ —	$ —

See accompanying notes to unaudited financial statements.

Agile Therapeutics, Inc.
Notes to Unaudited Financial Statements
June 30, 2019
(in thousands, except share and per share data)

1. Organization and Description of Business

Nature of Operations

Agile Therapeutics, Inc. ("Agile" or the "Company") was incorporated in Delaware on December 22, 1997. Agile is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. The Company's activities since inception have consisted principally of raising capital and performing research and development, including development of the Company's lead product candidate, Twirla®, also known as AG200-15. The Company is headquartered in Princeton, New Jersey.

The Company's lead product candidate, Twirla is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. The Company is seeking approval by the U.S. Food and Drug Administration (the "FDA") of the new drug application, (the "NDA") for Twirla, which was resubmitted in May 2019. The NDA has been assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 16, 2019. 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 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 June 30, 2019, the Company had an accumulated deficit of approximately $249.9 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 8), 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, which denied the Company's appeal on July 20, 2018. The Company then escalated its appeal to the Office of New Drugs ("OND").

Agile Therapeutics, Inc.
Notes to Unaudited Financial Statements
June 30, 2019
(in thousands, except share and per share data)

1. Organization and Description of Business (Continued)

In October 2018, the OND formally denied the Company's appeal and provided a path forward that may not require that the Company 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. DBRUP later agreed that Twirla would show adequate adhesion if it demonstrated statistical non-inferiority to Xulane by a margin of less than +0.15. On February 11, 2019, the Company announced the top-line results of the comparative wear study, which demonstrated that Twirla was statistically non-inferior to Xulane. The wear study suggested by OND to address adhesion provides a path forward but is not intended to address efficacy. 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. The FDA has notified the Company that they plan to convene a meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee, or BRUDAC, which is the advisory committee for contraceptive products, on October 30, 2019 to discuss the Twirla NDA.

The Company believes that its cash and cash equivalents as of June 30, 2019 will be sufficient to meet its operating requirements through the end of 2019. The Company will require additional capital to fund operating needs for 2020 and beyond including, 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 International, Inc. ("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 2020 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, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern.

As of June 30, 2019, the Company had cash and cash equivalents of $10.6 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.

The unaudited financial statements as of June 30, 2019 have been prepared under the assumption that the Company will continue as a going concern for the next 12 months. The Company's ability to continue as a going concern is dependent upon its uncertain ability to obtain additional equity and/or debt financing and reduce expenditures. The accompanying financial statements as of June 30, 2019 do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements.

Agile Therapeutics, Inc.
Notes to Unaudited Financial Statements
June 30, 2019
(in thousands, except share and per share data)

1. Organization and Description of Business (Continued)

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, 2018 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 six months ended June 30, 2019 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, 2018 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 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 June 30, 2019.

Agile Therapeutics, Inc.
Notes to Unaudited Financial Statements
June 30, 2019
(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

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. Prior to January 1, 2019, warrants with non-standard anti-dilution provisions (referred to as down round protection) were classified as liabilities and re-measured each reporting period. On January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2017-11 *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part 1) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception,* which indicates that a down round feature no longer precludes equity classification when assessing whether an investment is indexed to an entity's own stock. The Company used a modified retrospective approach to adoption, which does not restate its financial statements as of the prior year end (December 31, 2018). The cumulative effect of adoption of ASU 2017-11 resulted in an adjustment to accumulated deficit as of January 1, 2019 of $213 with a corresponding adjustment to additional paid-in capital. As of June 30, 2019, 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 7) are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. As of June 30, 2019, there were outstanding 180,274 warrants to purchase common stock at $5.89 per share related to this debt financing. These warrants expire on February 24, 2020.

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 or, in some cases, above 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

Agile Therapeutics, Inc.
Notes to Unaudited Financial Statements
June 30, 2019
(in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

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.

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 six months ended June 30, 2019 and 2018, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	June 30,	
	2019	2018
Common stock warrants	242,779	242,779
Unvested restricted stock units	—	147,554
Common stock options	7,526,820	5,702,976
Total	7,769,599	6,093,309

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. The recent accounting pronouncements did not have a material impact of the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

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:

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3. Fair Value Measurements (Continued)

- 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 June 30, 2019 and December 31, 2018.

	Level 1	Level 2	Level 3
June 30, 2019			
Assets:			
Cash and cash equivalents	$ 10,512	$ —	$ —
Total assets at fair value	$ 10,512	$ —	$ —

	Level 1	Level 2	Level 3
December 31, 2018			
Assets:			
Cash and cash equivalents	$ 7,776	$ —	$ —
Total assets at fair value	$ 7,776	$ —	$ —
Liabilities:			
Common stock warrants	$ —	$ —	$ —
Total liabilities at fair value	$ —	$ —	$ —

As indicated in Note 2, on January 1, 2019, the Company adopted the provisions of ASU 2017-11 to account for the down round feature of its warrants issued in connection with its initial public offering in May 2014. As a result of the adoption of ASU 2017-11, effective January 1, 2019, the Company no longer measures these warrants at fair value.

The significant assumptions used in preparing the option pricing model for valuing the Company's warrants as of December 31, 2018 include (i) volatility (70.0%), (ii) risk free interest rate of 2.57% (estimated using treasury bonds with a 1-year life), (iii) strike price ($6.00) for the common stock warrants, (iv) fair value of common stock ($0.58) and (v) expected life (1 year).

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3. Fair Value Measurements (Continued)

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

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

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

	June 30, 2019	December 31, 2018
Prepaid insurance	$ 102	$ 484
Other	76	123
Total prepaid expenses	$ 178	$ 607

5. Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2019	December 31, 2018
Employee bonuses	$ 540	$ 621
Accrued retention bonus	—	638
Accrued professional fees and other	263	84
Total accrued liabilities	$ 803	$ 1,343

6. Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statement of operations. The Company adopted ASU No. 2016-02 on January 1, 2019. The Company recorded a lease asset and lease liability of approximately $0.3 million on its balance sheet as of January 1, 2019, with no material impact on its statement of operations.

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6. Leases (Continued)

The Company has no finance leases and one operating lease for office space in Princeton, NJ. Operating lease expense was $48 and $97 for the three and six months ended June 30, 2019, respectively.

Operating cash flows used for operating leases during the three and six months ended June 30, 2019 were $35 and $75, respectively. As of June 30, 2019, the weighted-average remaining lease term was 1.4 years and the weighted-average discount rate was 21.2%.

Future minimum lease payments under non-cancellable leases as of June 30, 2019 were as follows:

Remainder of 2019	$	100
2020		191
Total	$	291
Less: Interest		(42)
Present value of lease liability	$	249

7. Loan and Security Agreement

Hercules Capital, Inc.

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

The First Amendment revised the Term Loan's maturity date to be on December 1, 2018. In connection with the execution of the First Amendment, the Company paid Hercules a facility fee of $165. The facility fee represented a debt issue cost, which was reflected as a reduction to the carrying amount of the loan payable in accordance with ASU 2015-03. Such issue costs were amortized to interest expense over the life of the Term Loan using the effective interest method.

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

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.

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7. Loan and Security Agreement (Continued)

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

Interest expense on the Hercules Loan Agreement including the accretion of the value of the related warrants, accrual of term loan back-end fee and amortization of the deferred financing costs was $0 for the three and six months ended June 30, 2019 and was approximately $320 and $689 for the three and six months ended June 30, 2018, respectively.

8. Stockholders' Equity

Shelf Registration Statement

On November 2, 2018, 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 $100.0 million (the "2018 Shelf Registration Statement"). On November 14, 2018, the 2018 Shelf Registration Statement was declared effective by the SEC. In the future, the Company may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the 2018 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

Private Placement

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

ATM Sales Agreement

In January 2019, the Company entered into a common stock sales agreement (the "Sales Agreement") under which the Company may sell up to an aggregate of $10.0 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). The Company agreed to pay a commission of 3% of the gross proceeds of any common stock sold under the Sales Agreement. For the three months ended June 30, 2019, the Company sold 992,072 shares of common stock under the ATM agreement, resulting in net proceeds of approximately $1.4 million. For the six months ended June 30, 2019, the Company sold 1,658,046 shares of common stock under the Sales Agreement, resulting in net proceeds of approximately $2.2 million.

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8. Stockholders' Equity (Continued)

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 159	$ 338	$ 310	$ 689
General and administrative	320	649	659	1,417
Total	$ 479	$ 987	$ 969	$ 2,106

9. 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 used 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.

10. 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.

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10. Restructuring Costs (Continued)

Each employee who participated in the Retention Plan (the "Retention Plan Participants") and (i) remained continuously employed by the Company through December 31, 2018 or (ii) had been terminated by the Company other than for cause (as defined in an applicable employment agreement, or, if no employment agreement existed, as determined by the Company in good faith) prior to December 31, 2018, were paid a lump-sum cash payment in an amount determined by the compensation committee (the "Compensation Committee") of the Company's board of directors at the time of the adoption of the Retention Plan. The total amount of the cash portion of the Retention Plan was approximately $0.6 million and was paid out to the Retention Plan Participants in January 2019.

In addition, each Retention Plan Participant was 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 vests 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.

A summary of accrued restructuring costs, included as a component of accrued liabilities on the Company's unaudited June 30, 2019 balance sheet is as follows:

	December 31, 2018	Charges	Payments	June 30, 2019
2018 Restructuring (severance)	$ 638	$ —	$ (638)	$ —
Total	$ 638	$ —	$ (638)	$ —

11. 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 June 30, 2019, the Company has not recorded a provision for any contingent losses.

12. Subsequent Events

In July 2019, the Compensation Committee adopted a retention plan (the "2019 Retention Plan") for all employees (with the exception of the Chairman and Chief Executive Officer) in order to induce such employees to remain employed by the Company through the approval of the NDA for Twirla by the FDA (the "Approval"), which has a PDUFA goal date of November 16, 2019.

Each employee who participates in the 2019 Retention Plan and remains continuously employed by the Company through the Approval shall be paid a lump-sum cash payment in an amount determined for each eligible employee by the Compensation Committee at the time of the adoption of the 2019 Retention Plan. If an eligible employee terminates employment prior to the Approval for any reason, no such retention payment shall be made to the eligible employee. The total amount of the cash portion of the 2019 Retention Plan is approximately $0.3 million.

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

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12. Subsequent Events (Continued)

In addition, the vesting for the stock options granted in January 2019 have been amended for all employees holding such options who were employed on July 3, 2019 as follows: 50% of the option will vest on January 29, 2020, 25% on June 30, 2020 and the remaining 25% on December 31, 2020. The accelerated vesting will result in an increase to non-cash stock based compensation beginning in July 2019.

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, 2019. 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 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 short-term goal is to establish a market-leading franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on the planned initial approval of our lead product candidate, Twirla, also known as AG200-15 in the U.S. Twirla is a once-weekly prescription contraceptive patch that is at the end of Phase 3 clinical development. We resubmitted our new drug application, or NDA, for Twirla to the U.S. Food and Drug Administration, or FDA, in the second quarter of 2019 and have been assigned a Prescription Drug User Fee Act, or PDUFA, goal date of November 16, 2019.

Recent Regulatory History

We have had a long and complicated history seeking regulatory approval for Twirla in the U.S., which has included the submission of our NDA for Twirla twice (first in 2012 and again in 2017), the issuance of two complete response letters, or CRLs, from the FDA in 2013 and 2017, and the need to pursue formal dispute resolution with the FDA after the CRL issued in 2017. We expect to face significant challenges as we continue to pursue regulatory approval for Twirla, including an advisory committee review of the safety and efficacy of Twirla, including a discussion regarding the Pearl Index from our SECURE Phase 3 clinical trial that the FDA noted is substantially higher than other previously approved combined hormonal contraceptives, or CHCs, and a likely pre-approval inspection of our third-party manufacturer's facility, which must be successfully completed prior to approval. The FDA has notified us that they plan to convene a meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee, or BRUDAC, which is the advisory committee for contraceptive products, on October 30, 2019 to discuss the Twirla NDA.

On December 21, 2017, after completion of its review of our Twirla NDA, the FDA, issued the second CRL, or the 2017 CRL. The FDA's reasons for issuing the 2017 CRL related to cited deficiencies in the manufacturing process for Twirla and questions about our clinical *in vivo* adhesion properties. More specifically, the 2017 CRL identifies deficiencies relating to:

- quality control adhesion test methods for the Twirla manufacturing process;
- observations identified during an inspection of a facility of our third-party manufacturer, Corium, for the Twirla NDA that must be resolved; and
- questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results.

The 2017 CRL also contains recommendations on addressing the cited deficiencies including recommendations that the Company:

- develop 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;

- assess the *in vivo* adhesion properties demonstrated in the SECURE clinical trial; and
- address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates.

In addition, 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 for Twirla. The FDA expressed concern in the 2017 CRL regarding the implication of delays in patch application for real-world use. The 2017 CRL does not identify any specific issues relating to the safety of Twirla.

At our request, the Division of Bone, Reproductive and Urologic Products, or DBRUP, 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 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, but 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 were demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion.

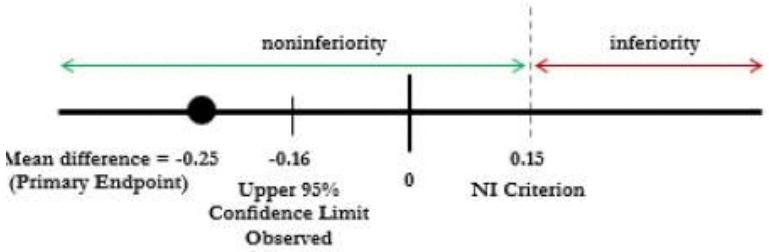
As recommended by OND, we met with DBRUP to discuss the specific design and success criteria of the comparative wear study. DBRUP agreed that Twirla would be considered statistically non-inferior to Xulane if the upper 95% confidence limit of the mean difference was less than +0.15. As agreed with DBRUP, we conducted a randomized, open-label, crossover adhesion study in healthy women aged 18 to 35 years with a Body Mass Index of less than 35 kg/m^2. Subjects were randomized to wear either Twirla or Xulane for the first week and then switched to the patch not initially worn for the second week. The study design followed the 2018 ANDA Guidance for Assessment of Adhesion entitled *Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.*

On February 11, 2019, we announced the top-line results of the comparative wear study. The study met the non-inferiority criterion set forth by the FDA by demonstrating an upper 95% confidence limit of -0.16.

Primary endpoint: mean adhesion scores for Twirla and Xulane

	Twirla		Xulane		Difference (Twirla — Xulane)		
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	One-sided upper 95% CL	Non-inferiority criterion met
Adhesion score in the Per Protocol population	77	0.14 (0.28)	77	0.39 (0.40)	-0.25 (0.23)	-0.16	Yes

Non-inferiority Scale



We resubmitted our Twirla NDA in the second quarter of 2019. Our resubmission included the results from the comparative wear study, additional information on our manufacturing process, and other analyses responding to the 2017 CRL. While our contract manufacturer, Corium, has provided the FDA with responses to each of the observations made during the FDA's 2017 facility inspection, we expect that the FDA will re-inspect Corium's facility during its review of the Twirla NDA before approval can be granted. The FDA has also informed us that the agency plans to hold a meeting of BRUDAC, which has been scheduled for October 30, 2019, to review of the safety and efficacy of Twirla, where we expect a discussion regarding the Pearl Index, an efficacy measurement from our SECURE Phase 3 clinical trial that the FDA noted is substantially higher than other previously approved CHCs.

We can make no assurances that the FDA will agree that the results of the comparative wear study demonstrate adequate adhesion of Twirla. If the FDA determines that Twirla's adhesion is still inadequate despite the results of the comparative wear study, it will likely not approve the Twirla NDA and require us to reformulate Twirla and conduct additional clinical or bioequivalence studies before we can, again, resubmit the Twirla NDA.

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 $9.8 million, $14.4 million and $20.9 million during the years ended December 31, 2018, 2017 and 2016, respectively. We incurred research and development expenses of $1.8 million and $2.4 million for the three months ended June 30, 2019 and 2018, respectively. We incurred research and development expenses of $4.7 million and $6.4 million for the six months ended June 30, 2019 and 2018, respectively. We anticipate that a portion of our operating expenses will continue to be related to research and development as we seek to complete the development of 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 June 30, 2019 and December 31, 2018, we had $10.6 million and $7.8 million in cash and cash equivalents, respectively.

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

In January 2019, we entered into a common stock sales agreement under which we may sell up to an aggregate of $10.0 million in gross proceeds through the sale of shares of common stock from time to time in "at-the-market" equity offerings (as defined in Rule 415 promulgated under the Securities Act of 1933, as amended). We agreed to pay a commission of 3% of the gross proceeds of any common stock sold under this agreement. During the six months ended June 30, 2019, we issued and sold a total of 1,658,046 shares of common stock under the common stock sales agreement resulting in net proceeds of approximately $2.2 million.

We have not generated any revenue and have never been profitable for any year. Our net loss was $19.8 million, $28.3 million and $28.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. Our net loss was $3.5 million and $5.3 million for the three months ended June 30, 2019 and 2018, respectively. Our net loss was $8.2 million and $12.2 million for the six months ended June 30, 2019 and 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 includes preparing for a scheduled FDA advisory committee meeting, completing the qualification and validation of our commercial manufacturing process, initiating pre-launch commercial activities, commercially launching Twirla, if approved, advancing our other potential product candidates and expanding our research and development programs. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We have halted all further work on our pipeline except for Twirla. We will require additional capital should we choose to advance the development of our other potential product candidates.

Going Concern

As of June 30, 2019, we had cash and cash equivalents of $10.6 million. We believe that our cash and cash equivalents as of June 30, 2019, will be sufficient to meet our projected operating requirements through the end of 2019. We will require additional capital to fund our operating needs for 2020 and beyond including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates.

Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. Pursuant to the receipt of the 2017 CRL, and the delay in the approval timeline for Twirla, our ability to continue operations for 2020 and beyond will depend on our ability to obtain additional funding, as to which no assurances can be given. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern. There can be no assurance that any financing by us can be realized, or if realized, what the terms of any such financing may be, or that any amount that we are able to raise will be adequate.

We continue to analyze strategic and financing alternatives, potential asset sales as well as mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we then may be unable to complete the 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 June 30, 2019 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional 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 also 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.

Research and development activities are central to our business model and to date, our research and development expenses have related primarily to the development of Twirla. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, as the majority of our past and planned expenses have been and will be in support of Twirla.

In 2019, we expect our research and development expenses to remain relatively consistent with 2018 expenses. Research and development expenses in 2019 will consist primarily of those costs associated with our wear study comparing the adhesion of Twirla and Xulane, preparation and resubmission of the NDA for Twirla, preparation for a pre-approval inspection of the manufacturing facility at Corium, preparation for an advisory committee meeting, the continued development and refinement of our commercial manufacturing process and responding to information requests expected to be received from the FDA as part of their review of our planned NDA resubmission. As a result of 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.

For the three months ended June 30, 2019 and 2018, our research and development expenses were approximately $1.8 million and $2.4 million, respectively. For the six months ended June 30, 2019 and 2018, our research and development expenses were approximately $4.7 million and $6.4 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended June 30,		Six months ended June 30,	
	(In thousands)			
	2019	2018	2019	2018
Clinical development	$ 83	$ 190	$ 1,581	$ 431
Regulatory	429	223	690	336
Personnel related	449	619	940	1,326
Manufacturing - commercialization	654	998	1,119	3,491
Manufacturing	5	45	20	99
Stock-based compensation	159	338	310	689
Total research and development expenses	$ 1,779	$ 2,413	$ 4,660	$ 6,372

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

Consistent with our previous NDA resubmission in 2017, our resubmission of the NDA responding to the 2017 CRL has been categorized as a Type 2 resubmission and we received a review period of six months from the date of resubmission of the NDA and the FDA assigned a PDUFA goal date of November 16, 2019. 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 obtaining additional capital, the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to developing and seeking regulatory approval for Twirla. We will require additional capital to fund our operating needs for 2020 and beyond including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates.

General and Administrative Expenses

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

For the three months ended June 30, 2019 and 2018, our general and administrative expenses totaled approximately $1.8 million and $2.3 million, respectively. For the six months ended June 30, 2019 and 2018, our general and administrative expenses totaled approximately $3.6 million and $5.4 million, respectively. In January 2018, following our receipt of the 2017 CRL, we significantly scaled back our preparations for commercialization of Twirla, including commercial pre-launch activities, pending our ability to address the 2017 CRL and receive approval of Twirla. If Twirla is approved, we intend to commercialize Twirla in the United States through a direct sales force. We anticipate that our general and administrative expenses will increase in the future with the continued research, development and potential commercialization of Twirla, its planned line extensions, and any of our other potential product candidates, and as we operate as a public company. These increases will likely include increased selling and marketing costs, including payroll and operating costs, related to the commercial launch of Twirla, if approved, legal and accounting services, stock registration and printing fees, addition of new personnel to support compliance and communication needs, increased insurance premiums, outside consultants and investor relations. Additionally, if in the future we believe regulatory approval of Twirla or any of our other potential product candidates appears likely, we anticipate that we would begin preparations for commercial operations, which would result in an increase in payroll and other expenses, particularly with respect to the sales and marketing of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

	Three months ended June 30,		
	2019	2018	Change
Operating expenses:			
Research and development	$ 1,779	$ 2,413	$ (634)
General and administrative	1,768	2,318	(550)
Restructuring costs	—	416	(416)
Total operating expenses	3,547	5,147	(1,600)
Other income (expense)			
Interest income	63	101	(38)
Interest expense	—	(320)	320
Change in fair value of warrants	—	22	(22)
Total other income (expense), net	63	(197)	260
Loss before benefit from income taxes	(3,484)	(5,344)	1,860
Net loss	$ (3,484)	$ (5,344)	$ 1,860

Research and development expenses. Research and development expenses decreased by $0.6 million, or 26%, from $2.4 million for the three months ended June 30, 2018 to $1.8 million for the three months ended June 30, 2019. This decrease in research and development expenses was primarily due to the following:

- a decrease in manufacturing commercialization expenses of $0.3 million for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018. 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 stock compensation expense of $0.2 million for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants;

- a decrease in personnel-related expenses of $0.2 million for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts;

- a decrease in clinical development expenses of $0.1 million for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018. This decrease is primarily related to decreased clinical trial insurance expense; and

- an increase in regulatory expense of $0.2 million for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018. This increase is primarily related to consulting fees incurred associated with the resubmission of our NDA for Twirla as well costs associated with the preparation for the upcoming FDA advisory committee meeting.

General and administrative expenses. General and administrative expenses decreased by $0.5 million, or 24%, from $2.3 million for the three months ended June 30, 2018 to $1.8 million for the three months ended June 30, 2019. This decrease in general and administrative expense was primarily due to:

- a decrease in stock compensation expense of $0.3 million for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants; and

- a decrease in commercial development expense of $0.2 million for the three months ended June 30, 2019 as compared to the three months ended June 30, 2018. 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.

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 30% 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. 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 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. Restructuring costs of $0.4 million for the three months ended June 30, 2018 represent $380 thousand of severance-related costs and $36 thousand 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 three months ended June 30, 2018. Interest expense also included 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 $0.3 million, or 100%, from $0.3 million for the three months ended June 30, 2018 to $0 for the three months ended June 30, 2019. The decrease is the result of the completion of the repayment of the term loan with Hercules on December 1, 2018.

Comparison of the Six Months Ended June 30, 2019 and 2018

	Six months ended June 30,		
	2019	2018	Change
Operating expenses:			
Research and development	$ 4,660	$ 6,372	$ (1,712)
General and administrative	3,594	5,404	(1,810)
Restructuring costs	—	416	(416)
Total operating expenses	8,254	12,192	(3,938)
Other income (expense)			
Interest income	101	198	(97)
Interest expense	—	(689)	689
Change in fair value of warrants	—	29	(29)
Total other income (expense), net	101	(462)	563
Loss before benefit from income taxes	(8,153)	(12,654)	4,501
Benefit from income taxes	—	477	(477)
Net loss	$ (8,153)	$ (12,177)	$ 4,024

Research and development expenses. Research and development expenses decreased by $1.7 million, or 27%, from $6.4 million for the six months ended June 30, 2018 to $4.7 million for the six months ended June 30, 2019. This decrease in research and development expenses was primarily due to the following:

- a decrease in manufacturing commercialization expenses of $2.4 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. 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 personnel-related expenses of $0.4 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. This decrease is primarily the result of the reduction in workforce that was announced in June 2018 as part of our restructuring efforts;

- a decrease in stock compensation expense of $0.4 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants;

- an increase in clinical development expenses of $1.1 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. This increase primarily relates to the costs associated with the comparative wear study of Twirla and Xulane which was initiated and completed during the first quarter of 2019; and

- an increase in regulatory expense of $0.4 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. This increase is primarily related to consulting fees incurred associated with the resubmission of our NDA for Twirla as well costs associated with the preparation for the upcoming FDA advisory committee meeting.

General and administrative expenses. General and administrative expenses decreased by $1.8 million, or 33%, from $5.4 million for the six months ended June 30, 2018 to $3.6 million for the six months ended June 30, 2019. This decrease in general and administrative expense was primarily due to:

- a decrease in stock compensation expense of $0.8 million for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. This decrease is primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants;

- a decrease in commercial development expense of $0.6 million for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. 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; and

- a decrease in personnel-related expenses of $0.3 million for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018. 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 30% 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. 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 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. Restructuring costs of $0.4 million for the six months ended June 30, 2018 represent $380 thousand of severance-related costs and $36 thousand 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 six months ended June 30, 2018. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Hercules, the amortization of the deferred financing costs associated with the term loan and the accrual of the final payment due to Hercules. Interest expense decreased by $0.7 million, or 100%, from $0.7 million for the six months ended June 30, 2018 to $0 for the six months ended June 30, 2019. The decrease is the result of the completion of the repayment of the term loan with Hercules on December 1, 2018.

Benefit from income taxes. For the six months ended June 30, 2019 and 2018, we received $0 and $0.5 million, respectively, from the sale of New Jersey state net operating losses ("NOLs") as part of the Technology and Business Tax Certificate Program, or the Program. The Program enables approved biotechnology companies to sell their unused Net Operating Loss Carryovers and unused Research and Development Tax Credits for at least 80% of the value of the tax benefits to unaffiliated, profitable corporate taxpayers in the State of New Jersey. The New Jersey Economic Development Authority and the New Jersey Department of the Treasury's Division of Taxation administer the Program. We 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 June 30, 2019, we had cash and cash equivalents totaling $10.6 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:

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	$ (7,339)	$ (9,908)
Net cash used in investing activities	—	(316)
Net cash provided by (used in) financing activities	10,074	(3,263)
Net increase (decrease) in cash and cash equivalents	$ 2,735	$ (13,487)

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 $7.3 million for the six months ended June 30, 2019 and consisted primarily of a net loss of $8.2 million, offset by non-cash stock-based compensation expense of $1.0 million. Net cash used in operating activities was $9.9 million for the six months ended June 30, 2018 and consisted primarily of a net loss of $12.2 million, which was offset by non-cash stock-based compensation expense of $2.1 million and non-cash interest expense of $0.3 million. Cash used in operations for the six months ended June 30, 2018 was offset, in part, by the proceeds received from the sale of New Jersey NOLs. The decreased clinical development expenses were offset by increased commercial development and commercial manufacturing expenses related to the initialization of pre-commercialization activities for Twirla.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 and 2018 was $0 and $0.3 million, respectively. Cash used in investing activities for the six months ended June 30, 2018 primarily represents the acquisition of equipment to be used in the commercialization of Twirla, if approved.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2019 was $10.1 million which primarily represented net proceeds of $7.8 million received from the issuance of 8,426,750 shares of our common stock in a private placement and net proceeds of approximately $2.2 million from the sale of a total of 1,658,046 shares of our common stock through an at-the-market, or ATM, sales program. Net cash used in financing activities for the six months ended June 30, 2018 was $3.3 million, which primarily represented principal payments under the Hercules loan agreement, which began on February 1, 2017.

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, which was completed in October 2018.

We resubmitted our Twirla NDA responding to the 2017 CRL in the second quarter of 2019. Consistent with our previous NDA resubmission in 2017, our resubmission has been categorized as a Type 2 resubmission and we received a review period of six months from the NDA resubmission date with an assigned PDUFA goal date of November 16, 2019. 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 BRUDAC, which has been scheduled for October 30, 2019.

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. During 2019, as described above, we raised approximately $10.1 million though a private placement of common stock and sales of common stock through our ATM sales program.

We believe that our cash and cash equivalents as of June 30, 2019 will be sufficient to meet our projected operating requirements through the end of 2019. We will require additional capital to fund our operating needs for 2020 and beyond including, among other items, the resumption and completion of our commercial plan for Twirla, which primarily includes the validation of our commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of our other potential product candidates. We 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.

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:

- prepare for and participate in the review of the safety and efficacy of Twirla at a meeting of BRUDAC;
- seek marketing approval for Twirla in the United States;
- establish a sales and marketing infrastructure to commercialize Twirla in the United States, if approved;
- complete the equipment qualification and validation related to the expansion of Corium's manufacturing facility in preparation for potential commercial operations;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

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 of Twirla, including, among other things, manufacturing scale up, FDA review of the NDA for Twirla and commercialization of Twirla, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Twirla. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of Twirla;
- the costs of the equipment qualification and validation related to the expansion of Corium's manufacturing facility in preparation for potential commercial operations;
- the costs of future commercialization activities, including the commercial launch, product sales, marketing, manufacturing and distribution, for Twirla, if approved;
- the revenue, if any, received from commercial sales of Twirla, if approved;

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

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

We do not have any committed external source of funds. Until such time, if ever, as we can generate substantial cash flows from product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

Going Concern

Pursuant to the receipt of the 2017 CRL, and the delay in the approval timeline for Twirla, our ability to continue operations for 2020 and beyond will depend on our ability to obtain additional funding, as to which no assurances can be given. Based upon the foregoing, management has concluded that there is substantial doubt about our ability to continue as a going concern. 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 June 30, 2019, we had cash and cash equivalents of $10.6 million. Our future success depends on our ability to raise additional capital and/or implement various strategic alternatives. We continue to analyze strategic and financing alternatives, potential asset sales as well as mergers and acquisitions. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, whether through the issuance of equity or convertible debt securities, or any combination thereof, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including Twirla, or grant licenses on terms that may not be favorable to us. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities and may need to seek bankruptcy protection.

The unaudited financial statements as of June 30, 2019 have been prepared under the assumption that we will continue as a going concern for the next 12 months. Our ability to continue as a going concern is dependent upon our uncertain ability to obtain additional equity and/or debt financing and reduce expenditures. These unaudited financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of June 30, 2019 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease	$ 291	$ 204	$ 87	$ —	$ —
Total	$ 291	$ 204	$ 87	$ —	$ —

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.

Shelf Registration Statements

On June 30, 2018, the shelf registration statement we filed on June 19, 2015, which we refer to as the 2015 Shelf Registration Statement, expired. On November 2, 2018, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an aggregate amount of $100.0 million, which we refer to as the 2018 Shelf Registration Statement. On November 14, 2018, the 2018 Shelf Registration Statement was declared effective by the SEC.

On January 23, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $10.0 million of shares of our common stock. During the six months ended June 30, 2019, we sold a total of 1,658,046 shares of our common stock under the ATM program resulting in net proceeds of approximately $2.2 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 $10.6 million and $7.8 million at June 30, 2019 and December 31, 2018, respectively consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Our results of operations and cash flows are subject to fluctuations due to changes in interest rates. 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, 2019.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three and six months ended June 30, 2019.

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.

Part II: Other Information

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

There have been no material changes during the quarter ended June 30, 2019 to our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2018.

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.

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: August 1, 2019

Agile Therapeutics, Inc.

By: /s/ Alfred Altomari
Alfred Altomari
President and Chief Executive Officer (Principal Executive Officer)

Date: August 1, 2019

By: /s/ Scott M. Coiante
Scott M. Coiante
Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alfred Altomari, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Agile Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 1, 2019

/s/ Alfred Altomari
Alfred Altomari
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott M. Coiante, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Agile Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 1, 2019

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
AGILE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Alfred Altomari, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 1, 2019

/s/ Alfred Altomari
Alfred Altomari
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

STATEMENT OF CHIEF ACCOUNTING OFFICER OF
AGILE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Agile Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Scott M. Coiante, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 1, 2019

/s/ Scott M. Coiante
Scott M. Coiante
Chief Financial Officer
Principal Financial and Accounting Officer