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 March 31, 2020

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 87,213,212 shares of the registrant's common stock, $0.0001 par value, outstanding as of May 1, 2020.

Agile Therapeutics, Inc.
Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2020

Table of Contents

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 manufacturing and commercialization of Twirla®, the potential market uptake of Twirla® and the development of our potential product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our potential product candidates, the legal and regulatory landscape impacting our business, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this 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 ability to successfully launch and commercialize Twirla;
- our ability along with the ability of our third-party manufacturer, Corium International, Inc., or Corium, to complete successfully the scale up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
- the rate and degree of market acceptance of Twirla and any of our product candidates;
- the size and growth of the markets for Twirla and our product candidates and our ability to serve those markets;
- the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as the effects of the COVID-19 pandemic on our potential customer base;
- regulatory and legislative developments in the United States and foreign countries;
- our available cash and our ability to obtain additional funding to fund our business plan without delay;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our inability to timely obtain from Corium sufficient quantities or quality of Twirla and our potential product candidates or other materials required for a clinical trial or other tests and studies;

- the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla;

- the performance and financial condition of Corium or any of its suppliers;

- our ability to design and successfully complete a post marketing long term, prospective observational safety study comparing risks for venous thromboembolism, or VTE, and arterial thromboembolism, or ATE, in new users of Twirla to new users of oral combined hormonal contraceptives, or CHCs, and new users of Xulane in U.S. women of reproductive age using CHCs and conduct a small post marketing commitment, or PMC, study to assess the residual drug content and strength of Twirla;

- our ability to maintain regulatory approval of Twirla and our ability to obtain regulatory approval of our potential product candidates, and the labeling under any approval we obtain;

- our ability to obtain and maintain intellectual property protection for Twirla and our product candidates;

- the success and timing of our clinical trials or other studies, including post marketing studies for Twirla;

- our plans to develop our other potential product candidates;

- the successful development of our sales and marketing capabilities, including our ability to recruit, train, and retain an effective sales force or failure to build out and implement an effective health care compliance program;

- our ability to retain key employees and recruit the additional personnel we will need to support our commercialization plan for Twirla; and

- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this 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, 2019 filed with the Securities and Exchange Commission on February 20, 2020 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, any such 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 93,925	$ 34,479
Prepaid expenses	672	840
Total current assets	94,597	35,319
Property and equipment, net	14,154	14,044
Right of use and other assets	136	177
Total assets	$ 108,887	$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,031	$ 1,819
Accrued expenses	649	1,804
Lease liability, current portion	128	172
Total current liabilities	2,808	3,795
Long-term debt	15,472	—
Total liabilities	18,280	3,795
Stockholders' equity		
Common stock, $.0001 par value, 150,000,000 shares authorized, 87,213,212 and 69,810,305 issued and outstanding at March 31, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	358,851	306,108
Accumulated deficit	(268,253)	(260,370)
Total stockholders' equity	90,607	45,745
Total liabilities and stockholders' equity	$ 108,887	$ 49,540

See accompanying notes to unaudited financial statements.

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

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 3,164	$ 2,881
General and administrative	4,453	1,826
Total operating expenses	7,617	4,707
Loss from operations	(7,617)	(4,707)
Other income (expense)		
Interest income	132	38
Interest expense	(398)	—
Total other income (expense), net	(266)	38
Loss before benefit from income taxes	(7,883)	(4,669)
Benefit from income taxes	—	—
Net loss	$ (7,883)	$ (4,669)
Net loss per share (basic and diluted)	$ (0.10)	$ (0.13)
Weighted-average common shares (basic and diluted)	76,652,190	37,308,232

See accompanying notes to unaudited financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount			
Balance December 31, 2019	69,810,305	$ 7	$ 306,108	$ (260,370)	$ 45,745
Share-based compensation - stock options and RSUs	—	—	621	—	621
Issuance of common stock in public offering, net of expenses	17,250,000	2	48,433	—	48,435
Issuance of common stock upon exercise of stock options	152,907	—	119	—	119
Warrants issued in connection with long-term debt	—	—	3,570	—	3,570
Net loss	—	—	—	(7,883)	(7,883)
Balance March 31, 2020	87,213,212	$ 9	$ 358,851	$ (268,253)	$ 90,607

See accompanying notes to unaudited financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount			
Balance December 31, 2018	34,377,329	$ 3	$ 261,722	$ (241,551)	$ 20,174
Adjustment to derivative 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

See accompanying notes to unaudited financial statements.

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

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (7,883)	$ (4,669)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4	5
Amortization	40	38
Noncash stock-based compensation	621	490
Noncash interest	101	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	168	229
Accounts payable and accrued expenses	(891)	(1,015)
Lease liability	(44)	(39)
Net cash used in operating activities	(7,884)	(4,961)
Cash flows from investing activities:		
Acquisition of property and equipment	(164)	—
Net cash used in investing activities	(164)	—
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	—	860
Proceeds from issuance of common stock in public offering, net of offering costs	48,434	—
Proceeds from issuance of long-term debt	20,000	—
Debt financing costs paid	(1,059)	
Proceeds from exercise of stock options	119	—
Net cash provided by financing activities	67,494	8,670
Net increase in cash and cash equivalents	59,446	3,709
Cash and cash equivalents, beginning of period	34,479	7,851
Cash and cash equivalents, end of period	$ 93,925	$ 11,560
Supplemental disclosure of noncash financing activities		
Warrants issued in connection with long-term debt	$ 3,570	—
Supplemental cash flow information		
Interest paid	$ 297	$ —
Cash paid for income taxes	$ —	$ —

See accompanying notes to unaudited financial statements.

1. Organization and Description of Business

Nature of Operations

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

The Company's sole approved product, Twirla®, also known as AG200 15, is a once weekly prescription contraceptive patch that received approval from the U.S. Food and Drug Administration, or FDA in February 2020. Substantially all of the Company's resources are currently dedicated to commercializing Twirla in the United States. The Company has not generated product revenue to date and is subject to a number of risks similar to those of other early stage companies, including, but not limited to, dependence on key individuals, the difficulties and uncertainties inherent in the development of commercially usable products, market acceptance of products, protection of proprietary technology, the potential need to obtain additional capital necessary to fund the development of its products, competition from larger companies and compliance with the FDA and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. The Company has incurred operating losses and negative cash flows from operating activities each year since inception. As of March 31, 2020, the Company had an accumulated deficit of approximately $268 million.

The Company expects to continue to incur significant expenses and increased operating losses for the foreseeable future and that its operating expenses will increase substantially in connection with its ongoing activities, as the Company:

- establishes a sales and marketing infrastructure to commercialize Twirla in the United States;
- continues the equipment pre-validation and validation process related to Corium's manufacturing facility in preparation for commercial operations;
- continues to evaluate additional line extensions for Twirla and initiates development of potential product candidates in addition to Twirla;
- maintains, leverages and expands the Company's intellectual property portfolio; and
- adds operational, financial and management information systems and personnel, including personnel to support the Company's product development and future commercialization efforts.

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.

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared by the Company 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 has 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, 2019 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 presented. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the operating results for the full fiscal year or any future period.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. Based on the Company's current business plan and ability to get Twirla launched, the Company believes that its cash and cash equivalents as of March 31, 2020 will be sufficient to meet its projected operating requirements through the end of 2021. If the COVID-19 outbreak or other factors impact the Company's current business plan or its ability to generate revenue from the launch of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

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, 2019 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.

Risks and Uncertainties

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

It should be noted that current public health threats could adversely affect the Company's ongoing or planned business operations. In particular, the World Health Organization has declared the outbreak of a novel strain of coronavirus, now referred to as COVID-19, a pandemic resulting in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures the Company has taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt the Company's business and could delay the Company's commercialization timeline. The Company cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if the Company or any of the third parties with whom it engages, including personnel at third-party manufacturing facilities and other third parties with whom the Company conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timeline presently planned could be materially and adversely impacted. While it is unknown how long these conditions will last and what the complete effect will be on the Company, to date, the Company has not experienced a significant impact on its plans and the related timelines. The Company will continue to closely monitor events as they develop and evaluate alternative, mitigating measures it can implement if needed.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash and cash equivalents are held in United States financial institutions. Cash and cash equivalents include money market funds that invest primarily in commercial paper and U.S. government and U.S. government agency obligations.

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

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash and cash equivalents are carried at fair value (see Note 3).

Other financial instruments, including accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Property and Equipment

Property and equipment, consisting of manufacturing, office and computer equipment, is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line, method over the estimated useful lives of the assets.

Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which costs are incurred. Improvements and additions are capitalized in accordance with Company policy.

Long-Lived Assets

In accordance with ASC 360, *Property, Plant and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management does not believe that there has been any impairment of the carrying value of any long-lived assets as of March 31, 2020.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expense consists primarily of costs related to personnel, including salaries and other personnel-related expenses, expenses related to manufacturing, clinical trial expenses, consulting fees and support services used in drug development. All research and development costs are charged to operations as incurred in accordance with ASC 730, *Research and Development*.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Deferred Financing Costs

Costs directly attributable to the Company's senior secured term loan (see Note 7) are deferred and reported as a reduction of the related term loan. These costs represent a 1% facility fee paid directly to the lender, legal fees and other costs related to the term loan and are being amortized over the term of the loan. Amortization of deferred financing costs charged to interest expense was approximately $23 for the three months ended March 31, 2020.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents. All cash and cash equivalents are held in business checking and money market accounts in United States financial institutions the balances of which exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts. The Company believes it is not exposed to significant credit risks on cash and cash equivalents. The Company has no financial instruments with off balance sheet risk of accounting loss.

Warrants

The Company accounts for its warrants to purchase common stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*. 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 Non-controlling Interests with a Scope Exception*, which indicate 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.

The warrants issued in connection with the Company's debt financing completed in February 2015 are classified as a component of stockholders' equity. The value of such warrants was determined using the Black-Scholes option-pricing model. These warrants expired without being exercised on February 24, 2020.

In connection with entering into a senior secured term loan facility in February 2020, the Company issued warrants to purchase 1,400,000 shares of its common stock. These warrant instruments qualify for equity classification and have been allocated based upon the relative fair value of the base instrument and the warrant. See Note 7 for additional information.

Income Taxes

The Company accounts for deferred taxes using the asset and liability method as specified by ASC 740, *Income Taxes*. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and the tax basis of assets and liabilities, operating losses and tax credit carryforwards. Deferred income taxes are measured using the enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company has adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions which prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Company has no uncertain tax positions as of March 31, 2020 that qualify for either recognition or disclosure in the financial statements under this guidance.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to no less than the fair value of the shares at grant date. Compensation cost is recognized for all share-based payments granted and is based on the grant-date fair value estimated using the weighted-average assumption of the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company elects to account for forfeitures when they occur. The equity instrument is not considered to be issued until the instrument vests. As a result, compensation cost is recognized over the requisite service period with an offsetting credit to additional paid-in capital.

The Company also awards restricted stock units ("RSUs") to employees and its board of directors. RSUs are generally subject to forfeiture if employment terminates prior to the completion of the vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse.

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 the diluted net loss per share calculation, common stock warrants, unvested RSUs and stock options are considered to be potentially dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the three months ended March 31, 2020 and 2019, respectively, because to do so would be anti-dilutive (in common equivalent shares):

	March 31,	
	2020	2019
Common stock warrants	1,400,000	242,779
Unvested restricted stock units	52,651	—
Common stock options	8,460,835	7,236,183
Total	9,913,486	7,478,962

Recent Accounting Pronouncements

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

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

3. Fair Value Measurements

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

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

- Level 1 — 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 or liabilities.

The following table sets forth the Company's financial instruments measured at fair value by level within the fair value hierarchy as of March 31, 2020 and December 31, 2019.

	Level 1	Level 2	Level 3
March 31, 2020			
Assets:			
Cash and cash equivalents	$ 93,925	$ —	$ —
Total assets at fair value	$ 93,925	$ —	$ —

	Level 1	Level 2	Level 3
December 31, 2019			
Assets:			
Cash and cash equivalents	$ 34,479	$ —	$ —
Total assets at fair value	$ 34,479	$ —	$ —

There were no transfers between Level 1, 2 or 3 during 2020 or 2019.

4. Prepaid Expenses

Prepaid expenses consist of the following:

	March 31, 2020	December 31, 2019
Prepaid insurance	$ 397	$ 656
Other	275	184
Total prepaid expenses	$ 672	$ 840

5. Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2020	December 31, 2019
Employee bonuses	$ 325	$ 1,437
Accrued professional fees and other	324	367
Total accrued liabilities	$ 649	$ 1,804

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.

The Company has no finance leases and one operating lease for office space in Princeton, NJ. Operating lease expense was $48 and $48 for the three months ended March 31, 2020 and 2019, respectively.

Operating cash flows used for operating leases during the three months ended March 31, 2020 and 2019 were $44 and $39, respectively. As of March 31, 2020, the weighted-average remaining lease term was 0.67 years and the weighted average discount rate was 21.2%.

Future minimum lease payments under non-cancellable leases as of March 31, 2020 were as follows:

Remainder of 2020	$	139
Total	$	139
Less: Interest		(11)
Present value of lease liability	$	128

7. Credit Agreement and Guaranty

On February 10, 2020 (the "Closing Date"), the Company entered into a Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP, a related party ("Perceptive"), for a senior secured term loan credit facility of up to $35.0 million, (the "Perceptive Credit Agreement"). A first tranche of $5.0 million was funded on execution of the Perceptive Credit Agreement. A second tranche of $15.0 million was funded as a result of the approval of Twirla by the FDA. Another $15.0 million tranche will be available to the Company based on the achievement of certain revenue milestones.

The facility will mature on February 10, 2024 ("Maturity Date"). The Company is scheduled to make interest-only payments on the loans under the Perceptive Credit Agreement until February 10, 2023. Thereafter, the Company is required to make monthly principal payments in an amount equal to 1.50% of the principal amount of the outstanding loans until February 10, 2024.

Borrowings under the Perceptive Credit Agreement will accrue interest at an annual rate equal to the London Interbank Offered Rate for one-month deposits ("LIBOR") plus 10.25%, provided that LIBOR shall not be less than 1.5%. The rate of interest in effect as of the Closing Date and at March 31, 2020 was 11.75%. Upon the occurrence and during the continuance of any event of default under the Perceptive Credit Agreement, the interest rate automatically increases by 3.0% per annum.

The Company may prepay any outstanding loans in whole or in part. Any such prepayment of the loans is subject to a prepayment fee of 10.0% if such prepayment occurs on or prior to February 10, 2021; 8.0% if such prepayment occurs after February 10, 2021 and on or prior to February 10, 2022; 4.0% if such prepayment occurs after February 10, 2022 and on or prior to February 10, 2023; and 2.0% if such prepayment occurs after February 10, 2023 and prior to February 10, 2024.

All of the Company's obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property.

The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customary for similar financings. The negative covenants restrict or limit the ability of the Company to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's business activities; make certain investments or restricted payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, the Company must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending March 31, 2021, report revenues for the trailing 12-month period that exceed the amounts set forth in the Perceptive Credit Agreement, which range from $3.8 million for the fiscal quarter ending March 31, 2021 to $93.5 million for the fiscal quarter ending December 31, 2023. At March 31, 2020, the Company was in compliance with all of the covenants contained in the Perceptive Credit Agreement.

In connection with the Perceptive Credit Agreement, the Company issued to Perceptive two warrants to purchase an aggregate of 1,400,000 shares of the Company's common stock (the "Perceptive Warrants"). The first warrant is exercisable for 700,000 shares of Common Stock at an exercise price of $3.74 per share. The second warrant is exercisable for 700,000 shares of Common Stock at an exercise price of $4.67 per share. The Perceptive Warrants contain anti-dilution provisions and other warrant holder protections. The Perceptive Warrants are not exercisable to the extent that Perceptive would beneficially own more than 19.99% of the Company's common stock as a result of the exercise. The Perceptive Warrants expire on February 10, 2027.

The Company allocated the proceeds of $20.0 million in accordance with ASC 470 based on the relative fair values of the debt and warrants. The relative fair value of the warrants of approximately $3.6 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 warrants issued to Perceptive include (i) volatility (70.0%), (ii) risk free interest rate of 1.47% (estimated using treasury bonds with a 3-year life), (iii) strike prices of $3.74 and $4.67 for the common stock warrants, (iv) fair value of common stock ($4.01) and (v) expected life (7 years). The fair value of the warrants as well as the debt issue costs incurred in connection with the entry into the Perceptive Credit Agreement, including a facility fee of 1% of the total amount of loans available under the facility, are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet as detailed below.

	March 31, 2020
Notes payable	$ 20,000
Debt issuance costs	(1,036)
Warrant discount	(3,492)
Long-term debt	$ 15,472

The fair value of the warrants and the debt issue costs are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of $101 for the three months ended March 31, 2020.

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.

Public Offerings

In February 2020, the Company completed a public offering of 17,250,000 shares of its common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 million.

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

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. During the three months ended March 31, 2019, the Company issued and sold 665,974 shares of common stock under the Sales Agreement resulting in net proceeds to the Company of approximately $860. All such shares were sold during February and March 2019.

Stock-Based Compensation Expense

Stock-based compensation expense was allocated as follows:

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 198	$ 151
General and administrative	423	339
Total	$ 621	$ 490

9. Income Taxes

On March 27, 2020, the US government enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) which includes numerous modifications to income tax provisions, including a limitation on business interest expense and net operating loss provisions and the acceleration of alternative minimum tax credits. Given the Company's history of losses, the CARES Act is not expected to have a material impact on its income tax provision.

10. 2019 Retention Plan

In July 2019, the Company adopted a retention plan (the "2019 Retention Plan") for all employees (with the exception of the Chairman and Chief Executive Officer) in order to induce such employees to remain employed by the Company through at least the extended PDUFA goal date of February 14, 2020.

Each employee who participated in the 2019 Retention Plan and remained continuously employed by the Company through the approval of Twirla was to 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 terminated employment prior to the approval for any reason, no such retention payment was payable to the eligible employee. With the approval of Twirla in February, the cash portion of the 2019 Retention Plan in the amount of approximately $0.3 million was expensed and paid to each eligible employee in February 2020.

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

In addition, the vesting schedule for the stock options granted in January 2019 was amended for all employees (with the exception of the Chairman and Chief Executive Officer) 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.

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 March 31, 2020, the Company has not recorded a provision for any contingent losses.

12. Subsequent Events

On April 30, 2020, the Company entered into a Manufacturing and Commercialization Agreement ("the Commercialization Agreement") with Corium, Inc. for the manufacture and supply of Twirla. Under the terms of the Commercialization Agreement, Corium is to be the exclusive supplier of Twirla for ten years. The Commercialization Agreement includes a quarterly minimum purchase commitment and a fixed price per unit for two years depending on annual purchase volume.

On April 30, 2020, the Company and inVentiv Commercial Services, LLC ("inVentiv," and together with the Company, the "Parties") entered into a project agreement (the "Project Agreement") pursuant to that certain Master Services Agreement, by and between the Parties, dated as of October 11, 2017. Pursuant to the Project Agreement, inVentiv will provide a field force of sales representatives to provide certain detailing services, sales operation services, compliance services and training services with respect to Twirla to the Company in exchange for an up-front implementation fee and a fixed annual fee. The Project Agreement terminates automatically on the second anniversary of the date of the first activity undertaken by inVentiv to detail Twirla (the "Deployment Date") unless earlier extended upon the mutual written agreement of the Parties. The Company may terminate the Project Agreement for any reason upon timely notice after the first anniversary of the Deployment Date; provided, however, that if the Company terminates the Project Agreement prior to the eighteen month anniversary of the Deployment Date, the Company will be obligated to pay inVentiv a termination fee, the amount of which varies depending on the date of termination.

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 February 20, 2020. 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 potential product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Twirla, our first and only approved product, is a once-weekly prescription combination hormonal contraceptive patch. Twirla is designed using our proprietary transdermal patch technology, called Skinfusion®, designed with properties to optimize patch adhesion and patient wearability, which may help support compliance while, for the first time, delivering a dose of estrogen consistent with commonly prescribed combined hormonal contraceptives, or CHCs. We believe there is an unmet market need for a contraceptive patch that is designed to deliver approximately 30 mcg of estrogen and 120 mcg of progestin in a convenient dosage form that may support compliance in a non-invasive fashion.

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

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

With the approval of Twirla we are now focused on our transition from a clinical development stage company to a commercial company. During 2020, we plan to continue the implementation of our commercialization plan for Twirla and to manage the growth of our company. Our near-term plan for the commercialization of Twirla includes:

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

Our short-term goal is to establish an initial franchise in the multi-billion-dollar U.S. hormonal contraceptive market built on approval of Twirla in the U.S. Our resources are currently focused on the commercialization of Twirla. To that end, our goal is to begin the pre-validation and validation of the commercial manufacturing process in the first half of 2020, manufacture three validation batches of Twirla and complete the process in the second half of 2020. We intend to ship product to wholesalers in the fourth quarter of 2020. At the same time, we will prepare for the availability of commercial product supply. We also expect to explore the advancement of our existing pipeline and its possible expansion through business development activities.

In the first quarter of 2020, we began work to engage with third party payors to gain coverage and reimbursement for Twirla, advanced the pre-validation work on our commercial manufacturing process for Twirla, and entered into an agreement with our third-party logistics provider for Twirla distribution services.

In the second quarter of 2020, we completed production of the planned manufacturing pre-validation batch of Twirla and subject to completion of the final quality assurance testing, we expect to begin the validation process. On April 30, 2020, we entered into a definitive agreement with our contract manufacturer, Corium, for the commercial manufacture and supply of Twirla. On April 30, 2020, we entered into an agreement with inVentiv Commercial Services, a Syneos Health group company, or inVentiv, to provide a contract sales force and related sales services for Twirla. We plan to begin hiring and training an initial sales team, which we estimate to be in the range of 70 to 100 persons. We continue to monitor the current public health crisis and evaluate with our partner inVentiv the exact size and specific implementation plan for our sales team, including the use of remote detailing services.

A summary of our current priorities are as follows:

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

It should be noted that current public health threats could adversely affect our ongoing or planned business operations. In particular, the World Health Organization has declared the outbreak of a novel strain of coronavirus, now referred to as COVID-19, a pandemic resulting in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and could delay our

commercialization timeline. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. While it is unknown how long these conditions will last and what the complete effect will be on the Company, to date, we have not experienced a significant impact on our plans and the related timelines. We will continue to closely monitor events as they develop and evaluate alternative, mitigating measures we can implement if needed.

Financial Overview

Since our inception in 1997, we have devoted substantial resources to developing and seeking regulatory approval for Twirla, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. We incurred research and development expenses of $9.9 million, $9.8 million and $14.4 million during the years ended December 31, 2019, 2018 and 2017, respectively. We incurred research and development expenses of $3.2 million and $2.9 million for the three months ended March 31, 2020 and 2019, respectively. While we anticipate that a portion of our operating expenses will continue to be related to research and development as we complete the pre-validation manufacturing activities related to Twirla, conduct our Phase 4 study, and plan the development of our pipeline, we expect our operating expenses to substantially shift towards commercialization. A substantial amount of our resources are currently dedicated to completing manufacturing validation and commercializing Twirla.

Moving forward, we plan to monitor our spending closely. We expect operating expenses for the full year 2020 to be in the range of $52.0 million to $56.0 million, with general and administrative expenses accounting for approximately 70% of the spending as we build out our commercial infrastructure. Net revenue in the fourth quarter of 2020, reflecting the initial launch of Twirla, is expected to be in the range of $4.0 million to $6.0 million. Based on our current business plan and our ability to get Twirla launched, we believe that our cash and cash equivalents as of March 31, 2020, will be sufficient to meet our projected operating requirements through the end of 2021. If the COVID-19 outbreak or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations.

We have funded our operations primarily through sales of common stock, convertible preferred stock, convertible promissory notes and term loans. As of March 31, 2020 and December 31, 2019, we had $93.9 million and $34.5 million in cash and cash equivalents, respectively.

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

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

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

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

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

In February 2020, we completed a public offering of 17,250,000 shares of our common stock at a price of $3.00 per share. Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 million.

We have not generated any revenue and have never been profitable for any year. Our net loss was $18.6 million, $19.8 million and $28.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our net loss was $7.9 million and $4.7 million for the three months ended March 31, 2020 and 2019, respectively. We expect to incur increased expenses and increasing operating losses for the foreseeable future as we commercialize Twirla. This includes completing the qualification and validation of our commercial manufacturing process, initiating pre-launch commercial activities, commercially launching Twirla, advancing our other potential product candidates and expanding our research and development programs.

We do not own any manufacturing facilities and rely on our contract manufacturer, Corium, for all aspects of the manufacturing of Twirla. We will need to continue to invest in the manufacturing process for Twirla, and incur significant expenses, in order to complete the validation of Corium's commercial manufacturing line for Twirla and be capable of supplying projected commercial quantities of Twirla. 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.

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.

For the three months ended March 31, 2020 and 2019, our research and development expenses were approximately $3.2 million and $2.9 million, respectively. The following table summarizes our research and development expenses by functional area.

	Three months ended March 31, (In thousands)	
	2020	2019
Clinical development	$ 177	$ 1,498
Regulatory	229	261
Personnel related	492	491
Manufacturing—commercialization	2,068	480
Stock-based compensation	198	151
Total research and development expenses	$ 3,164	$ 2,881

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 Twirla or our product candidates that obtain regulatory approval.

The duration, costs and timing of clinical trials and development of our other potential product candidates in addition to conducting required post-marketing studies for Twirla will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, the rate of subject enrollment, obtaining additional capital, and significant and changing government regulation. For the foreseeable future, we expect the current public health crisis to have an effect on the conduct of clinical trials. In addition, the probability of success for the development of any of our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, or experience issues with our manufacturing capabilities we could be required to expend significant additional financial resources and time with respect to the development of that product candidate. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential. Substantially all of our resources are currently dedicated to commercializing Twirla.

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 March 31, 2020 and 2019, our general and administrative expenses totaled approximately $4.5 million and $1.8 million, respectively. With the recent approval of Twirla, we intend to commercialize Twirla in the United States through a contract sales force. We anticipate that our general and administrative expenses will increase in the future with the commercialization of Twirla. These increases will likely include increased selling and marketing costs, including payroll and operating costs, related to the commercial launch of Twirla, legal and accounting services, stock registration and printing fees, addition of new personnel to

support compliance and communication needs, increased insurance premiums, outside consultants and investor relations.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

	Three months ended March 31,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 3,164	$ 2,881	$ 283
General and administrative	4,453	1,826	2,627
Total operating expenses	7,617	4,707	2,910
Other income (expense)			
Interest income	132	38	94
Interest expense	(398)	—	(398)
Total other income (expense), net	(266)	38	(304)
Loss before benefit from income taxes	(7,883)	(4,669)	(3,214)
Net loss	$ (7,883)	$ (4,669)	$ (3,214)

Research and development expenses. Research and development expenses increased by $0.3 million, or 9.8%, from $2.9 million for the three months ended March 31, 2019 to $3.2 million for the three months ended March 31, 2020. This increase in research and development expenses was primarily due to the following:

- an increase in manufacturing commercialization expenses of $1.6 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. This increase reflects costs to complete manufacturing development, process improvements, and pre-validation work for the commercial manufacturing of Twirla by Corium, our contract manufacturer; and

- a decrease in clinical development expenses of $1.3 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. This decrease is primarily related to decreased costs associated with the comparative wear study of Twirla and Xulane which was initiated and completed during the three months ended March 31, 2019.

General and administrative expenses. General and administrative expenses increased by $2.6 million, or 144%, from $1.8 million for the three months ended March 31, 2019 to $4.5 million for the three months ended March 31, 2020. This increase in general and administrative expense was primarily due to:

- an increase in commercial development expense of $1.7 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. This increase relates to the resumption of our pre-commercialization activities such as brand building, advocacy, market research and consulting;

- an increase in salaries and wages of $0.4 million, primarily related to retention bonuses expensed and paid in the three months ended March 31, 2020;

- an increase in professional fee expense of $0.2 million primarily related to recruiting fees and increased use of financial consultants;

- an increase in stock compensation expense of $0.1 million for the three months ended March 31, 2020 compared to the three months ended March 31, 2019. This increase is primarily the result of a higher stock price associated with the January 2020 stock option grants as compared to the January 20198 stock option grants; and

- an increase in D&O insurance of $0.1 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019.

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

Interest expense. Interest expense is primarily attributable to our term loan with Perceptive for the three months ended March 31, 2020. Interest expense also includes the amortization of the discount associated with allocating value to the common stock warrants issued to Perceptive and the amortization of the deferred financing costs associated with the term loan. Interest expense increased by $0.4 million from $0 for the three months ended, March 31, 2019 to $0.4 million for the three months ended March 31, 2020.

Liquidity and Capital Resources

At March 31, 2020, we had cash and cash equivalents totaling $93.9 million. We invest our cash equivalents in short-term highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (7,884)	$ (4,961)
Net cash used in investing activities	(164)	—
Net cash provided by financing activities	67,494	8,670
Net increase in cash and cash equivalents	$ 59,446	$ 3,709

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 $7.9 million for the three months ended March 31, 2020 and consisted primarily of a net loss of $7.9 million, offset by non-cash stock-based compensation expense of $0.6 million, $0.1 million of other non-cash charges, and a net decrease in operating assets and liabilities of $0.8 million. Net cash used in operating activities was $5.0 million for the three months ended March 31, 2019 and consisted primarily of a net loss of $4.7 million, which was offset by non-cash stock-based compensation expense of $0.5 million and a net decrease in operating assets and liabilities of $0.8 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2020 and 2019 was $0.2 million and $0, respectively. Cash used in investing activities for the three months ended March 31, 2020 primarily represents the acquisition of equipment to be used in the commercialization of Twirla.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2020 was $67.5 million which primarily represented net proceeds of $48.4 million received from the issuance of 17,250,000 shares of our common

stock through a public offering, and proceeds of $20.0 million from the Perceptive term loan. These proceeds were partially offset by debt financing costs of $1.0 million. Net cash provided by financing activities for the three months ended March 31, 2019 was $8.7 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 $0.9 million from the sale of 665,974 shares of our common stock through an at-the-market, or ATM, sales program.

Funding Requirements and Other Liquidity Matters

Based on our current business plan and ability to get Twirla launched, we believe that our cash and cash equivalents as of March 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. If the COVID-19 outbreak or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations.

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

- establish a sales and marketing infrastructure to commercialize Twirla in the United States;
- continue the pre-validation and validation process related to Corium's manufacturing facility in preparation for commercial operations;
- continue to evaluate additional line extensions for Twirla and initiate development of potential product candidates in addition to Twirla;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of March 31, 2020 that will affect our future liquidity:

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease	$ 139	$ 139	$ —	$ —	$ —
Total	$ 139	$ 139	$ —	$ —	$ —

Our operating lease commitment relates to our lease of office space in Princeton, New Jersey, which is set to expire in November 2020. We are currently seeking new facilities or considering expanding existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Shelf Registration Statement

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

On January 23, 2019, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering an at-the-market offering program we entered into for the sale of up to $10.0 million of shares of our common stock. In

the year ended December 31, 2019, we sold a total of 1,801,528 shares of our common stock under the ATM program resulting in net proceeds of approximately $2.5 million.

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

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

On February 21, 2020, we filed a prospectus supplement to our 2018 Shelf Registration Statement registering a public offering of 17,250,000 shares of common stock at a price of $3.00 per share Proceeds from the public offering, net of underwriting discounts, commissions and offering expenses were approximately $48.4 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 $93.9 million and $34.5 million at March 31, 2020 and December 31, 2019, 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 three months ended March 31, 2020.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts and agreements. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three months ended March 31, 2020.

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.

The following updated risk factors should be considered in addition to our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2019:

Risks Related to our Business Operations and Industry

The outbreak of the novel strain of coronavirus, or COVID-19, or other similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including on our anticipated commercial launch of Twirla®.

In December 2019, a novel strain of coronavirus (SARS-CoV-2), now referred to as COVID-19, surfaced in Wuhan, China. Since then, the virus has spread globally to multiple countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive on many aspects of society, and it has resulted in and will likely continue to result in significant disruptions to global business activities and capital markets around the world.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely affect our business, including our plans to clinically develop and commercialize our products. We may not be able to meet expectations with respect to our anticipated commercial launch of Twirla, our first approved product, which we plan to begin manufacturing on a commercial scale in the second half of 2020. For example, global business interruptions resulting from COVID-19 may adversely impact our third-party manufacturer, Corium, whom we rely upon for the manufacture of Twirla, as well as its suppliers of raw materials. As a result, we may not be able to obtain sufficient quantities of Twirla, which could impair our ability to commercialize Twirla and conduct the post-marketing studies requested by the U.S. Food and Drug Administration, or the FDA, in connection with the approval of Twirla. In addition, if there are continued or future disruptions, our third-party manufacturers may not be able to supply our other potential product candidates, which would adversely affect our research and development activities

Further, many jurisdictions have implemented travel restrictions and expansive social distancing orders. These measures may have a material adverse impact on the third-party consultants who assist us with our sales and

marketing functions, as well as on our ability to develop our own sales and marketing infrastructure. For example, such social distancing orders could limit the ability of sales representatives to interact with healthcare providers and also restrict the ability of patients to interact with their healthcare providers. This could negatively affect our ability to commercialize Twirla as well as market our other potential product candidates.

Delays in the ability to manufacture commercial supplies of Twirla and to implement a sales force for Twirla could also adversely affect our financial position. Based on our current business plan and ability to get Twirla launched, we believe that our cash and cash equivalents as of March 31, 2020 will be sufficient to meet our projected operating requirements through the end of 2021. If the COVID-19 outbreak or other factors impact our current business plan or our ability to generate revenue from the launch of Twirla, we believe we have the ability to revise our commercial plans, including curtailing sales and marketing spending, to allow us to continue to fund our operations. However, significant delays in the timelines to manufacture commercial supply of Twirla, and/or the ability to implement a salesforce that can engage with healthcare providers could delay, or even prevent, our ability to generate revenue, which in turn could require us to raise additional capital if the revisions to our commercial plans are inadequate or management determines that it is necessary.

Additionally, certain of our clinical activities, including the post-marketing studies requested by the FDA in connection with the approval of Twirla may be delayed or interrupted, compromising our ability to maintain regulatory approval for Twirla and our future ability to obtain marketing approval for our other potential product candidates. Any of these factors could significantly impair our ability to generate revenue in the future and to attain and maintain profitability.

We are continuing to monitor and assess the real and potential effects of the COVID-19 pandemic on our business, including with respect to our expected timing for commercialization of Twirla. However, the ultimate extent to which COVID-19 impacts our business will depend upon future developments which are highly uncertain and cannot be accurately predicted at this time, such as the ultimate geographic spread of the virus, the severity of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or mitigate its impact, and the effectiveness of actions taken in the United States and other countries to treat the disease.

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 them 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: May 5, 2020

Agile Therapeutics, Inc.

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

Date: May 5, 2020

By: /s/ Dennis P. Reilly
Dennis P. Reilly
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: May 5, 2020

/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, Dennis P. Reilly, 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: May 5, 2020

/s/ Dennis P. Reilly
Dennis P. Reilly
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 March 31, 2020 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: May 5, 2020

/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 March 31, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, Dennis P. Reilly, 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: May 5, 2020

/s/ Dennis P. Reilly
Dennis P. Reilly
Chief Financial Officer
Principal Financial and Accounting Officer