UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

May 2, 2019
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey** (Address of principal executive offices)	**08540** (Zip Code)

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

(Former name or former address, if changed since last report)

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

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company x

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

Item 2.02 Results of Operations and Financial Condition

On May 2, 2019, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2019 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated May 2, 2019.

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 hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: May 2, 2019

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: Chairman and Chief Executive Officer

Exhibit 99.1

Agile Therapeutics Reports First Quarter 2019 Financial Results

Company Plans to Resubmit Twirla® NDA in Second Quarter of 2019

Cash Expected to Enable Company to Fund Operations into the Fourth Quarter of 2019

PRINCETON, New Jersey, May 2, 2019 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2019 and provided a corporate update.

First quarter 2019 and other recent corporate developments:

Twirla® Update

- *Comparative Wear Trial Completed:* On February 11, 2019, the Company announced topline results of a comparative wear study of Twirla® and Xulane®, which demonstrated that Twirla was statistically non-inferior to Xulane, a product the U.S. Food and Drug Administration (FDA) considers to have adequate adhesion. The Company had previously reported that in its December 2018 meeting with FDA's Division of Bone, Reproductive and Urologic Products, (DBRUP), DBRUP agreed that Twirla would show adequate adhesion if it demonstrated statistical non-inferiority to Xulane in this study.

- *In Vivo Adhesion Data from Two Phase 1 Studies Presented:* An abstract presenting data from two Phase 1 in vivo wear studies on the adhesion of Twirla was selected for a poster presentation during the 2nd Annual Formulation & Drug Delivery USA Congress. The poster, titled *"Results of Two Phase 1 Clinical Trials on the Adhesion Profile of AG200-15, An Investigational Transdermal Contraceptive Delivery System,"* was presented by lead author Terrance Ocheltree, PhD, a former FDA Reviewer and Director of the Division of New Drug Quality Assessment II at the FDA.

- *New Drug Application (NDA) Resubmission Plans*: The Company plans to resubmit its Twirla NDA in the second quarter of 2019 and seek approval of the NDA in the fourth quarter of 2019. The planned resubmission is intended to be a complete response to the complete response letter the Company received from the FDA in December 2017 (2017 CRL) and will include the results from the comparative wear study, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL.

Financing Update

- On March 4, 2019, the Company completed the sale of approximately 8.4 million shares of common stock at $0.93 per share to an institutional accredited investor through a private placement, resulting in net proceeds of approximately $7.8 million.

"We are pleased with the progress we made on our business plan during the first quarter of 2019" said Al Altomari, Chairman and Chief Executive Officer of Agile. "Between the successful completion of the comparative wear study requested by the FDA and funds raised through our private placement of common stock, we believe we can execute our regulatory strategy to seek the approval of Twirla. We continue to believe that Twirla, if approved, will provide women with an important contraception option they do not currently have — a once-weekly contraceptive patch designed to deliver a low dose of estrogen."

First Quarter Financial Results

- **Cash and cash equivalents:** As of March 31, 2019, Agile had $11.6 million of cash and cash equivalents compared to $7.8 million of cash and cash equivalents as of December 31, 2018. The Company believes its cash and cash equivalents as of March 31, 2019 will be sufficient to meet its projected operating requirements into the fourth quarter of 2019. The Company will require additional capital to fund operating needs for the remainder of the fourth quarter of 2019 and beyond, which will include, among other items, the completion of its commercial plan for Twirla, if approved, which primarily includes validation of the commercial manufacturing process and the commercial launch, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were $2.9 million for the quarter ended March 31, 2019, compared to $4.0 million for the comparable period in 2018. The decrease in R&D expenses was primarily due to a decrease in manufacturing and commercialization expenses reflecting reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL offset, in part, by the cost of the comparative wear study that was initiated and completed in the first quarter of 2019.

- **General and administrative (G&A) expenses:** G&A expenses were $1.8 million for the quarter ended March 31, 2019, compared to $3.1 million for the comparable period in 2018. The decrease in G&A expenses was primarily due to the suspension of pre-commercialization activities as well as decreased personnel costs as a result of the receipt of the 2017 CRL.

- **Net loss:** Net loss was $4.7 million, or $0.13 per share, for the quarter ended March 31, 2019, compared to a net loss of $6.8 million, or $0.20 per share, for the quarter ended March 31, 2018.

- **Shares Outstanding:** At March 31, 2019, Agile had 43,615,257 shares of common stock outstanding.

About Twirla® (AG200-15)

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational low-dose, once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen, and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. Agile received the 2017 CRL from the FDA relating to the NDA for Twirla. The Company plans to resubmit the Twirla NDA in the second quarter of 2019.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is an investigational low-dose, non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions and projected cash position. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes

to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond the fourth quarter of 2019, which raises substantial doubt about our ability to continue as a going concern, and which, in turn, may create negative reactions to the price of our common stock making it more difficult to obtain financing in the future, our expectations about Twirla and its NDA, and the use of the net proceeds of our recently completed private placement. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward looking statements are subject to risks and uncertainties including risks related to our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern, our ability to adequately and timely respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our data do not support resubmission or approval of Twirla NDA and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the 2017 CRL, our ability to resubmit the Twirla NDA and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain, our ability to obtain a favorable Advisory Committee vote in the likely event the FDA requires an Advisory Committee to review the benefit and risk profile of Twirla, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing, our third-party manufacturer, Corium International, Inc.'s (Corium) inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility and to pass a likely FDA pre-approval inspection, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, our ability to retain key employees, regulatory and legislative developments in the United States and foreign countries, which could include, among other things, a government shutdown, our plans to commercialize Twirla and develop our other potential product candidates, the size and growth of the potential markets for our product candidates and our ability to serve those markets, the rate and degree of market acceptance of any of our product candidates, our ability to obtain and maintain intellectual property protection for our product candidates, the successful development of our sales and marketing capabilities, our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, our ability to successfully implement our strategy and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Agile Therapeutics

Contact: Investor Relations — 609-683-1880

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 11,560	$ 7,851
Prepaid expenses	378	607
Total current assets	11,938	8,458
Property and equipment, net	13,911	13,916
Right of use and other assets	284	18
Total assets	$ 26,133	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,183	$ 2,218
Lease liability, current portion	157	—
Total current liabilities	1,340	2,218
Lease liability, long-term	128	—
Stockholders' equity		
Common stock	4	3
Additional paid-in capital	271,094	261,722
Accumulated deficit	(246,433)	(241,551)
Total stockholders' equity	24,665	20,174
Total liabilities and stockholders' equity	$ 26,133	$ 22,392

Agile Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 2,881	$ 3,960
General and administrative	1,826	3,086
Total operating expenses	4,707	7,046
Loss from operations	(4,707)	(7,046)
Other income (expense)		
Interest expense	—	(368)
Interest income	38	97
Change in fair value of warrants	—	7
Loss before benefit from income taxes	(4,669)	(7,310)
Benefit from income taxes	—	477
Net loss	$ (4,669)	$ (6,833)
Net loss per share - basic and diluted	$ (0.13)	$ (0.20)
Weighted-average shares outstanding — basic and diluted	37,308,232	34,229,162