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

August 1, 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**	**08540**
(Address of principal executive offices)	(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 August 1, 2019, the Company issued a press release announcing its financial results for the second quarter ended June 30, 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 August 1, 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: August 1, 2019

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

Exhibit 99.1

Agile Therapeutics Reports Second Quarter 2019 Financial Results

FDA Assigned PDUFA (Prescription Drug User Fee Act) Goal Date is November 16, 2019

Cash Expected to Enable Company to Fund Operations through the End of 2019

PRINCETON, New Jersey, August 1, 2019 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and six months ended June 30, 2019 and provided a corporate update.

Second quarter 2019 and other recent corporate developments:

Twirla® Update

- *Acceptance of New Drug Application (NDA) Resubmission of Twirla:* The Company resubmitted its Twirla NDA on May 16, 2019. The NDA resubmission was intended to be a complete response to the complete response letter the Company received from the U.S. Food and Drug Administration (FDA) in December 2017 (2017 CRL) and included the results from a comparative wear study, which was recommended by the FDA, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL. The FDA informed the Company that it considers the resubmission to be a complete, class 2 response to the CRL and established November 16, 2019 as the Prescription Drug User Fee Act (PDUFA) goal date.

- *Advisory Committee Meeting for Twirla NDA:* In June 2019, the Company announced that a meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee of the FDA has been scheduled for October 30, 2019 to review the Company's NDA for Twirla.

- *Combined Safety Data from Three Phase 3 Studies Presented:* A poster presenting the combined safety data from three Phase 3 studies of Twirla (AG200-15) was presented in an ePoster session at the 2019 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG). The poster, titled *"Safety of AG200-15, an Investigational Transdermal Patch in Three Phase 3 Studies,"* was presented by lead author Anita Nelson, M.D., Professor and Chair of Obstetrics and Gynecology, Western University of Health Sciences and a Principle Investigator for SECURE, the pivotal Phase 3 study of Twirla (AG200-15)

"The second quarter of 2019 was a very productive quarter for the Company" said Al Altomari, Chairman and Chief Executive Officer of Agile. "Between the resubmission and acceptance of our Twirla NDA as well as the announcement of the advisory committee meeting, we believe we are on track 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."

Second Quarter Financial Results

- **Cash and cash equivalents:** As of June 30, 2019, Agile had $10.6 million of cash and cash equivalents compared to $7.8 million of cash and cash equivalents as of December 31, 2018. During the quarter ended June 30, 2019, the Company raised net proceeds of approximately $1.4 million from the sale of 992,072 shares of common stock from its "at-the-market" equity offerings. The Company believes its cash and cash equivalents as of June 30, 2019 will be sufficient to meet its projected operating requirements through the end of 2019. The Company will require additional capital to fund operating needs for 2020 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 $1.8 million for the quarter ended June 30, 2019, compared to $2.4 million for the comparable period in 2018. The decrease in R&D expenses was primarily due to a decrease in manufacturing and commercialization expenses and a decrease in stock compensation expense. The reduction in manufacturing and commercialization expenses reflects reduced activity associated with the scale-up of the commercial manufacturing process which was implemented as a result of the receipt of the 2017 CRL. The decrease in stock compensation expense was primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants.

- **General and administrative (G&A) expenses:** G&A expenses were $1.8 million for the quarter ended June 30, 2019, compared to $2.3 million for the comparable period in 2018. The decrease in G&A expenses was primarily due to decreased stock compensation expense primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants and the suspension of pre-commercialization activities as a result of the receipt of the 2017 CRL.

- **Net loss:** Net loss was $3.5 million, or $0.08 per share, for the quarter ended June 30, 2019, compared to a net loss of $5.3 million, or $0.16 per share, for the quarter ended June 30, 2018.

- **Shares Outstanding:** At June 30, 2019, Agile had 44,632,329 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. The Company resubmitted the Twirla NDA in the second quarter of 2019 and has been assigned a November 16, 2019 PDUFA goal date.

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 approvability and subsequent availability of Twirla, the interpretation of data that supports the approval of Twirla, the timing of our advisory committee meeting and of the FDA's review of the Twirla NDA, and the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations after the end 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. 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 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 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 obtain and maintain regulatory approval of Twirla, our ability to obtain a favorable advisory committee vote regarding the benefit and risk profile of Twirla, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing, the inability of our third-party manufacturer, Corium International, Inc. (Corium), to complete any work or provide any data and other information necessary to support the 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 inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, and 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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 10,586	$ 7,851
Prepaid expenses	178	607
Total current assets	10,764	8,458
Property and equipment, net	13,906	13,916
Right of use and other assets	250	18
Total assets	$ 24,920	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,607	$ 2,218
Lease liability, current portion	167	—
Total current liabilities	1,774	2,218
Lease liability, long-term	82	—
Stockholders' equity		
Common stock	4	3
Additional paid-in capital	272,977	261,722
Accumulated deficit	(249,917)	(241,551)
Total stockholders' equity	23,064	20,174
Total liabilities and stockholders' equity	$ 24,920	$ 22,392

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

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