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 3, 2018
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)

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 3, 2018, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2018 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 Current Report on Form 8-K (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 3, 2018.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated August 3, 2018.

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 3, 2018

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

Exhibit 99.1

Agile Therapeutics Reports Second Quarter 2018 Financial Results

Cash Expected to Enable Company to Fund Operations into Second Quarter 2019

PRINCETON, New Jersey, August 3, 2018 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and six months ended June 30, 2018 and provided a corporate update.

Second quarter 2018 and other recent corporate developments:

Twirla® Update — As previously announced, Agile initiated formal dispute resolution with the U.S. Food and Drug Administration's (FDA) Office of Drug Evaluation III (ODE III) on June 6, 2018 to appeal the complete response letter (CRL) the FDA issued in December 2017 relating to the New Drug Application (NDA) for Twirla (AG200-15), the Company's investigational non-daily, low-dose combination hormonal contraceptive patch. The Company initiated the formal dispute resolution process following an end-of-review meeting in April 2018 in which the FDA provided the Company with a more complete understanding of its assessment of the *in vivo* adhesion data for Twirla in the CRL. On July 24, 2018, the Company announced that FDA's ODE III had affirmed the position of the Division of Bone, Reproductive and Urologic Products (DBRUP) and denied the Company's appeal. The Company had appealed the decision communicated in the CRL that DBRUP's concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through the Company's proposed patient compliance programs. The Company will escalate its appeal to the Office of New Drugs (OND) and, potentially, additional levels of FDA management if necessary.

"We are focused on presenting and discussing our appeal with the Office of New Drugs and carefully managing our financial resources," said Al Altomari, Chairman and Chief Executive Officer of Agile. "We continue to believe that the *in vivo* adhesion data from our Phase 3 SECURE clinical trial is adequate for approval and that Twirla, if approved, will provide women with an important contraception option they do not currently have — a contraceptive patch designed to deliver a low dose of estrogen."

Second Quarter Financial Results

- **Cash and cash equivalents:** As of June 30, 2018, Agile had $22.5 million of cash and cash equivalents compared to $35.9 million of cash and cash equivalents as of December 31, 2017. In June 2018, the Company announced a reduction in its workforce and reductions on other planned operating expenses as the Company pursues formal dispute resolution. As a result of these planned cost reductions, the Company believes its cash and cash equivalents as of June 30, 2018, will be sufficient to meet its operating requirements into the second quarter of 2019. The Company will require additional capital to fund operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, the completion of its commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were $2.4 million for the quarter ended June 30, 2018, compared to $3.8 million for the comparable period in 2017. The decrease in R&D expenses was primarily due to decreased clinical development expenses as the Company's Phase 3 SECURE clinical trial for Twirla completed the close-out phase during 2017 as well as decreased regulatory expenses related to the preparation of the Company's NDA resubmission and response to the FDA's February 2013 CRL in June 2017.

- **General and administrative (G&A) expenses:** G&A expenses were $2.3 million for the quarter ended June 30, 2018, compared to $3.2 million for the comparable period in 2017. The decrease in G&A expenses was primarily due to the suspension of pre-commercialization activities as a result of the receipt of the CRL in December 2017.

- **Net loss:** Net loss was $5.3 million, or $0.16 per share for the quarter ended June 30, 2018, compared to a net loss of $7.4 million, or $0.26 per share for the quarter ended June 30, 2017.

- **Shares Outstanding:** At June 30, 2018, Agile had 34,377,329 shares of common stock outstanding.

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a 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. Agile received a complete response letter (CRL) from the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the FDA had on the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. As announced on May 18, 2018, Agile met with the FDA during a Type A meeting on April 16, 2018 to discuss the CRL and received the official end of review (EOR) minutes on May 15, 2018. The Company initiated formal dispute resolution with the FDA on June 6, 2018 in response to the FDA's position on Twirla's *in vivo* adhesion properties communicated in the EOR minutes. The Company believes the FDA provided guidance on a path forward for addressing the manufacturing issues related to Twirla.

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” 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 second 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 ability to succeed in formal dispute resolution with the FDA, which can be lengthy and expensive and the success of which is not guaranteed and our belief that Twirla’s adhesion profile is adequate for approval and a reformulation of Twirla is not necessary. 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 ability to manage costs and execute on our operational and budget plans, our ability to either succeed in our formal dispute resolution with the FDA, or, if we are unsuccessful, our ability to develop a reformulation that will address the FDA’s concerns, if we are required to reformulate Twirla, our ability to successfully complete an additional adhesion study and bioequivalence study, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review and approval of Twirla by the FDA, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, and unforeseen market factors or events in our clinical and manufacturing development plans 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 22,465	$ 35,952
Prepaid expenses	200	762
Total current assets	22,665	36,714
Property and equipment, net	13,924	13,863
Other assets	18	18
Total assets	$ 36,607	$ 50,595
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,829	$ 3,636
Loan payable, current portion	7,525	10,607
Warrant liability	—	29
Total liabilities	10,354	14,272
Stockholders’ equity		
Common stock	3	3
Additional paid-in capital	260,199	258,092
Accumulated deficit	(233,949)	(221,772)
Total stockholders’ equity	26,253	36,323
Total liabilities and stockholders’ equity	$ 36,607	$ 50,595

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended	Six Months Ended

	June 30,		June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 2,413	$ 3,798	$ 6,372	$ 8,519
General and administrative	2,318	3,198	5,404	5,603
Restructuring costs	416	—	416	—
Total operating expenses	5,147	6,996	12,192	14,122
Loss from operations	(5,147)	(6,996)	(12,192)	(14,122)
Other income (expense)				
Interest expense	(320)	(504)	(689)	(1,050)
Interest income	101	61	198	109
Change in fair value of warrants	22	(7)	29	102
Loss before benefit from income taxes	(5,344)	(7,446)	(12,654)	(14,961)
Benefit from income taxes	—	—	477	—
Net loss	$ (5,344)	$ (7,446)	$ (12,177)	$ (14,961)
Net loss per share - basic and diluted	$ (0.16)	$ (0.26)	$ (0.36)	$ (0.52)
Weighted-average shares outstanding —basic and diluted	34,277,601	28,802,112	34,253,515	28,785,827