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

July 28, 2017
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)

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 July 28, 2017, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2017 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 July 28, 2017.

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: July 28, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated July 28, 2017.

Exhibit 99.1

Agile Therapeutics Reports Second Quarter 2017 Financial Results

Cash Expected to Fund Operations into Q2 2018

FDA Assigns Prescription Drug User Fee Act (PDUFA) Goal Date of December 26, 2017

PRINCETON, New Jersey, July 28, 2017 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company today reported financial results for the three and six months ended June 30, 2017, and provided a corporate update for the second quarter 2017.

Second quarter 2017 and other recent corporate developments include:

- **Twirla® Update** — On June 27, 2017, the Company announced that it had resubmitted to the U.S. Food and Drug Administration (FDA) the New Drug Application (NDA) for Twirla, its investigational low-dose combined hormonal contraceptive patch (AG200-15). The Company resubmitted the NDA in response to a February 2013 Complete Response Letter (CRL) from the FDA. On July 27, 2017, the Company announced that the FDA had acknowledged the resubmitted NDA for Twirla as a complete response to the CRL, and provided a target Prescription Drug User Fee Act **(**PDUFA**)** goal date of December 26, 2017.

- **Securities Litigation —** On July 13, 2017, the previously-disclosed complaints that were filed in January 2017 in the United States District Court for the District of New Jersey on behalf of a putative class of investors who purchased Company stock from March 9, 2016 through January 3, 2017 were dismissed with prejudice as to all defendants. The complaints alleged violations of the federal securities laws based on public statements made regarding the Company's Phase 3 SECURE clinical trial and sought as damages an unspecified amount to be determined at trial. The Company has denied all allegations in the complaints. Following consolidation of the lawsuits and appointment of a lead plaintiff for the putative class, in June 2017, the lead plaintiff agreed to dismiss the consolidated case with prejudice voluntarily, without payment of any consideration and with each side bearing its own attorney fees and costs.

"We made excellent progress during the second quarter of 2017, most notably, with the successful submission and acceptance of the NDA resubmission for Twirla to the FDA. We are pleased with the assigned target PDUFA goal date of December 26, 2017. These accomplishments have set the stage for what we expect will be an important year for the company as we move closer to potentially commercializing our novel low-dose contraceptive patch and providing an important new contraceptive option for women," said Al Altomari, Chairman and CEO of Agile. "We look forward to working with the FDA in moving Twirla through the regulatory review process and will continue to prudently manage our capital resources as we execute our business plan, which we expect will allow us to fund operations into the second quarter of 2018."

Second Quarter Financial Results

- **Cash and cash equivalents:** As of June 30, 2017, Agile had $33.9 million of cash and cash equivalents compared to $48.8 million of cash and cash equivalents as of December 31, 2016. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of June 30, 2017, will be sufficient to meet its operating requirements into the second quarter of 2018. The Company's

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current business plan assumes the FDA review of the Company's resubmission of the Twirla NDA will be completed on the target PDUFA action date, and that pre-commercial activities and initiation of validation of its commercial manufacturing process will be coordinated with the timing of commercialization of Twirla, if approved. The Company will require additional capital for the commercial launch of Twirla, if approved, and for the development of its other product candidates. In the event of unforeseen changes to its planned timelines and business plan assumptions, as stated above, the Company still believes it has the ability to continue funding its operations into the second quarter of 2018 by postponing certain planned commercial and validation spending.

- **Research and development (R&D) expenses:** R&D expenses were $3.8 million for the quarter ended June 30, 2017, compared to $5.6 million for the comparable period in 2016. The decrease in R&D expense was primarily due to decreased clinical development expenses as the Company's Phase 3 SECURE clinical trial for Twirla continued the close-out phase. The decrease in clinical development expenses was offset, in part, by increased expenses associated with commercial manufacturing scale-up activities, which we expect to continue to increase in 2017.

- **General and administrative (G&A) expenses:** G&A expenses were $3.2 million for the quarter ended June 30, 2017, compared to $2.3 million for the comparable period in 2016. The increase in G&A expenses was primarily due to increased pre-commercialization activities, which we expect to continue to increase in 2017.

- **Net loss:** Net loss was $7.4 million, or $0.26 per share for the quarter ended June 30, 2017, compared to a net loss of $8.4 million, or $0.29 per share for the quarter ended June 30, 2016.

- **Shares Outstanding:** At June 30, 2017, Agile had 28,806,398 shares of common stock outstanding.

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 a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adhesion and patient wearability. For more information, please visit the company website at www.agiletherapeutics.com. The company may occasionally disseminate material, nonpublic information on the company website.

Forward-Looking Statement

Certain information contained in this press release includes “forward-looking statements” related to the Company’s clinical trials, regulatory submissions, projected cash position and potential market opportunity for its product candidates. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “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. 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. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional

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pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA; our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute the Company’s operational and budget plans, the FDA does not approve Twirla, the FDA’s timeline for review is not completed by the target PDUFA goal date, our ability to timely complete the qualification and validation of our commercial manufacturing process, the fact that our existing cash and cash equivalents will not be sufficient to fund our current and planned operations through the next 12 months, 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, and unforeseen events in our clinical and manufacturing development plans; and our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company’s Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. 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: Mary Coleman — 609-356-1921

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 33,938	$ 48,750
Prepaid expenses	525	2,768
Total current assets	34,463	51,518
Property and equipment, net	12,769	12,330
Other assets	18	18
Total assets	$ 47,250	$ 63,866
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,172	$ 5,402
Loan payable, current portion	5,981	5,104
Warrant liability	70	172
Total current liabilities	10,223	10,678
Loan payable, long-term	7,886	10,899
Stockholders’ equity		
Common stock	3	3
Additional paid-in capital	237,567	235,754
Accumulated deficit	(208,429)	(193,468)
Total stockholders’ equity	29,141	42,289
Total liabilities and stockholders’ equity	$ 47,250	$ 63,866

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,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 3,798	$ 5,577	$ 8,519	$ 10,505
General and administrative	3,198	2,264	5,603	4,316
Total operating expenses	6,996	7,841	14,122	14,821
Loss from operations	(6,996)	(7,841)	(14,122)	(14,821)
Other income (expense)				
Interest expense	(504)	(548)	(1,050)	(1,095)
Interest income	61	33	109	50
Change in fair value of warrants	(7)	(62)	102	130
Loss before benefit from income taxes	(7,446)	(8,418)	(14,961)	(15,736)
Benefit from income taxes	—	—	—	—
Net loss	$ (7,446)	$ (8,418)	$ (14,961)	$ (15,736)
Net loss per share - basic and diluted	$ (0.26)	$ (0.29)	$ (0.52)	$ (0.57)
Weighted-average shares outstanding —basic and diluted	28,802,112	28,744,004	28,785,827	27,785,113