

AGILE THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 03/12/18 for the Period Ending 03/12/18

Address	101 POOR FARM ROAD PRINCETON, NJ, 08540-1715
Telephone	609-683-1880
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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**

March 12, 2018

Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36464

(Commission
File Number)

23-2936302

(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- 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

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.

Item 2.02 Results of Operations and Financial Condition

On March 12, 2018, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2017 and an update on the Company’s operations. 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 March 12, 2018.

EXHIBIT INDEX

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99.1	Press release issued by Agile Therapeutics, Inc. dated March 12, 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: March 12, 2018

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

Agile Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results**Current Business Plan Expected to Enable Cash to Fund Operations through the end of 2018**

PRINCETON, New Jersey, March 12, 2018 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months and year ended December 31, 2017 and provided a corporate update.

Fourth quarter 2017 and other recent corporate developments include:

- **Twirla® Update** — On December 22, 2017, the Company announced that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) in response to the New Drug Application (NDA) resubmission for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15). The CRL stated that the FDA has determined that it could not approve the NDA in its present form due to deficiencies related to the manufacturing process for Twirla, and questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the phase 3 clinical trial results. Under the FDA's regulations, the Company is entitled to request a Type A meeting with the FDA within 90 days of receiving a CRL, and the FDA has a goal to grant the meeting date within 30 days of the meeting request. The Company has submitted a request for a Type A meeting to the FDA to discuss the deficiencies in the Twirla NDA and the regulatory path for approval of Twirla. The Company plans to provide an update on the outcome of the Type A meeting after it receives the official meeting minutes from the FDA and it will then be better able to determine when it will resubmit its Twirla NDA.

"We are focused on preparing for our upcoming meeting with the FDA to discuss the points identified in the CRL and a potential path forward for the approval of Twirla," stated Al Altomari, Chairman and Chief Executive Officer of Agile. "We believe that Twirla, if approved, will provide women with a new contraceptive option in the form of a patch that is designed to deliver a low dose of estrogen and offer greater convenience for women."

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2017, Agile had \$35.9 million of cash and cash equivalents compared to \$48.8 million of cash and cash equivalents as of December 31, 2016. In January 2018, in response to the 2017 CRL, the Company significantly scaled back equipment qualification and validation of its commercial manufacturing process and its other commercial pre-launch activities. Based on these actions and the Company's current business plan, the Company believes its cash and cash equivalents as of December 31, 2017, will be sufficient to meet its operating requirements through the end of 2018. The Company's current business plan assumes the resubmission of the Company's NDA for Twirla in the second quarter of 2018, a six-month FDA review of the NDA resubmission and resumption of both pre-launch commercial activities and pre-validation and validation of the commercial manufacturing process after Twirla approval, if the FDA approves Twirla. The Company will require additional capital to fund operating needs beyond 2018, 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.
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- **Research and development (R&D) expenses:** R&D expenses were \$2.7 million for the quarter ended December 31, 2017 and \$14.4 million for the year ended December 31, 2017, compared to \$5.5 million and \$20.9 million for the comparable periods 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 completed the close-out phase. The decrease in clinical development expenses was offset, in part, by increased expenses associated with commercial manufacturing scale-up activities.
- **General and administrative (G&A) expenses:** G&A expenses were \$3.3 million for the quarter ended December 31, 2017 and \$12.4 million for the year ended December 31, 2017, compared to \$2.3 million and \$8.8 million for the comparable periods in 2016. The increase in G&A expenses was primarily due to increased pre-commercialization activities.
- **Net loss:** Net loss was \$6.2 million, or \$0.18 per share for the quarter ended December 31, 2017, compared to a net loss of \$5.2 million, or \$0.18 per share for the quarter ended December 31, 2016. Net loss for the quarter ended December 31, 2016 includes a benefit from income taxes of approximately \$3.0 million, or \$0.11 per basic share related to the sale of the Company's New Jersey net operation losses through the State of New Jersey's Technology Business Tax Certificate Transfer Program. Net loss for the year ended December 31, 2017 was \$28.3 million, or \$0.91 per share, compared to a net loss of \$28.7 million or \$1.02 per share for the year ended December 31, 2016.
- **Shares Outstanding:** At December 31, 2017, Agile had 34,186,342 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 has 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. We 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 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," "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 our ability to adequately and timely respond to the deficiencies in the CRL issued by the FDA in December 2017 may be affected by whether any such response will be accepted by the FDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, the possibility that the FDA may require additional studies to address the concerns raised in the CRL (for example, if it is determined that the product adhesion concerns raised in the CRL are due to the design or formulation of the drug product, the FDA may recommend that we design a new transdermal system and conduct another clinical trial with the new transdermal system in a U.S. population, or

even if the FDA agrees with our position regarding the relationship between the *in vivo adhesion* properties of Twirla and the efficacy and safety results from our SECURE clinical trial, the FDA may still determine that the need for a convenient, contraceptive patch and the demonstrated efficacy of Twirla, including the pearl index from our SECURE clinical trial, do not outweigh the potential risks associated with the product, and therefore are not sufficient to support the approval of Twirla), or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA; our statements about the results of our clinical trial could be affected by the potential that there are changes in the interpretation of the data by the FDA (for example, the FDA continues to question the number of pregnancies included in our results and it may adjudicate additional pregnancies); our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute our operational and budget plans, if the FDA requires us to perform additional work or conduct additional studies prior to our resubmission of the NDA for Twirla, the fact that our existing cash and cash equivalents will not be sufficient to fund our current and planned operations beyond 2018, 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; our statements about the potential commercial opportunity could be affected by potential labeling restrictions, 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 our 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)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,952	\$ 48,750
Prepaid expenses	762	2,768
Total current assets	36,714	51,518
Property and equipment, net	13,863	12,330
Other assets	18	18
Total assets	<u>\$ 50,595</u>	<u>\$ 63,866</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,636	\$ 5,694
Loan payable, current portion	10,607	5,104
Warrant liability	29	172
Total current liabilities	14,272	10,970
Loan payable, long-term	—	10,607
Total liabilities	14,272	21,577
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	258,092	235,754
Accumulated deficit	(221,772)	(193,468)
Total stockholders' equity	36,323	42,289
Total liabilities and stockholders' equity	<u>\$ 50,595</u>	<u>\$ 63,866</u>

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 2,734	\$ 5,514	\$ 14,428	\$ 20,929
General and administrative	3,254	2,295	12,383	8,792
Total operating expenses	5,988	7,809	26,811	29,721
Loss from operations	(5,988)	(7,809)	(26,811)	(29,721)
Other income (expense)				
Interest expense, net	(314)	(533)	(1,636)	(2,329)
Change in fair value of warrants	62	66	143	234
Loss before benefit from income taxes	(6,240)	(8,276)	(28,304)	(31,816)
Benefit from income taxes	—	3,075	—	3,075
Net loss	\$ (6,240)	\$ (5,201)	\$ (28,304)	\$ (28,741)
Net loss per share - basic and diluted	\$ (0.18)	\$ (0.18)	\$ (0.91)	\$ (1.02)
Weighted-average shares outstanding —basic and diluted	34,183,772	28,758,025	30,940,831	28,273,331