
**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 9, 2016

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)).
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Item 2.02 Results of Operations and Financial Condition

On March 9, 2016, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2015 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by Agile Therapeutics, Inc. dated March 9, 2016.

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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 9, 2016

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

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by Agile Therapeutics, Inc. dated March 9, 2016.

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Agile Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results

Cash Expected to Fund Operations Through the End of 2017

PRINCETON, New Jersey, March 9, 2016 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today reported financial results for the three months and year ended December 31, 2015 and provided a corporate update for the fourth quarter 2015.

Fourth quarter 2015 and other recent corporate developments include:

- In December 2015, the Company announced that it had received net proceeds of approximately \$6.0 million in non-dilutive financing through the State of New Jersey's Technology Business Tax Certificate Transfer Program.
- In February 2016, the Company announced completion of a public offering of common stock whereby a total of 6,338,583 shares of common stock were sold at a public offering price of \$6.35 per share before underwriting discounts and commissions. The total net proceeds after deducting underwriting discounts and other expenses incurred in connection with the offering are expected to be approximately \$37.3 million from the offering.
- In February 2016, the Company announced the appointment of Ajit S. Shetty, Ph.D. to the Company's Board of Directors. Dr. Shetty spent 36 years at Johnson & Johnson in a wide range of global roles and brings significant pharmaceutical commercial and supply chain experience to the Company's Board.

"This past year was a productive one for Agile as we completed enrollment in our SECURE clinical trial and expanded our intellectual property portfolio," said Al Altomari, Chief Executive Officer and President of Agile. "We have continued our momentum into 2016 by strengthening our cash position through the completion of our common stock offering, and we believe we are now well-positioned to advance Twirla® through the clinic. We look forward to Twirla becoming the first low-dose combined hormonal contraceptive patch for women."

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2015, Agile had \$34.4 million of cash and cash equivalents compared to \$40.2 million of cash and cash equivalents as of December 31, 2014. In February 2016, Agile raised estimated net proceeds of approximately \$37.3 million in a public offering of common stock. Based on our current business plan, the Company believes its cash and cash equivalents as of December 31, 2015, along with the estimated net proceeds received from its February 2016 common stock offering will be sufficient to meet its operating requirements through the end of 2017. In addition, upon the achievement of certain clinical milestones, the Company would be eligible to draw an additional tranche of \$8.5 million under the terms of the loan and security agreement with Hercules Technology Growth Capital, Inc.
- **Research and development (R&D) expenses:** R&D expenses were \$6.9 million for the quarter ended December 31, 2015 and \$25.6 million for the year ended December 31, 2015, compared to \$5.0 million and \$13.4 million for the comparable periods in 2014. The increase in R&D expense was primarily due to clinical research organization costs associated with the ongoing Phase 3 clinical trial for Twirla.
- **General and administrative (G&A) expenses:** G&A expenses were \$2.3 million for the quarter ended December 31, 2015 and \$7.5 million for the year ended December 31, 2015, compared to \$1.5 million and \$5.2 million for the comparable periods in 2014. The increase in G&A expenses was primarily due to increased stock-based compensation expense associated with 2015 stock option grants as well as increased compensation expense and increased directors' and officers' insurance expense to support public company operations.
- **Net loss:** Net loss was \$3.9 million, or \$0.17 per basic share for the quarter ended December 31, 2015, compared to a net loss of \$6.8 million, or \$0.37 per basic share for the quarter ended December 31, 2014. The decrease in net loss per share for the quarter is primarily the result of a benefit from income taxes of approximately \$6.0 million, or \$0.27 per basic share related to the sale of our New Jersey net operating losses through the State of New Jersey's Technology Business Tax Certificate Transfer Program. Net loss for the year ended December 31, 2015 was \$30.3 million, or \$1.38 per basic share, compared to a net loss of \$16.1 million, or \$1.41 per basic share for the year ended December 31, 2014.
- **Shares Outstanding:** At December 31, 2015, Agile had 22,315,612 shares of common stock outstanding. An additional 6,338,583 shares of common stock were issued in connection with Agile's common stock offering which was completed in February 2016.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. 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 adherence and patient acceptability. 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, projected cash position, timeline for clinical trials 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 expectations 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. For example, 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, and unforeseen events in our clinical and manufacturing development plans; our statements about the timing of completion of our clinical trials and our ability to potentially commercialize our

product candidates, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; 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)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,395	\$ 40,182
Prepaid expenses	3,690	804
Total current assets	38,085	40,986
Property and equipment, net	12,318	12,046
Other assets, long-term	309	1,794
Total assets	<u>\$ 50,712</u>	<u>\$ 54,826</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,040	\$ 3,693
Loan payable, current portion	2,488	5,003
Warrant liability	406	296
Total current liabilities	7,934	8,992
Loan payable, long-term	13,035	9,828
Stockholders' equity		
Common stock	2	2
Additional paid-in capital	194,468	170,396
Accumulated deficit	(164,727)	(134,392)
Total stockholders' equity	29,743	36,006
Total liabilities and stockholders' equity	<u>\$ 50,712</u>	<u>\$ 54,826</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,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 6,914	\$ 4,977	\$ 25,622	\$ 13,365
General and administrative	2,251	1,547	7,467	5,150
Total operating expenses	9,165	6,524	33,089	18,515
Loss from operations	(9,165)	(6,524)	(33,089)	(18,515)
Interest expense, net	(551)	(391)	(2,072)	(1,563)
Change in fair value of warrants	(155)	70	(110)	348
Loss on extinguishment of debt	—	—	(1,036)	—
Loss before benefit from income taxes	(9,871)	(6,845)	(36,307)	(19,730)
Benefit from income taxes	5,972	—	5,972	3,653

Net loss	<u>\$ (3,899)</u>	<u>\$ (6,845)</u>	<u>\$ (30,335)</u>	<u>\$ (16,077)</u>
Net loss per common share:				
Basic and Diluted	<u>\$ (0.17)</u>	<u>\$ (0.37)</u>	<u>\$ (1.38)</u>	<u>\$ (1.41)</u>
Weighted-average shares outstanding:				
Basic and Diluted	<u>22,296,638</u>	<u>18,598,749</u>	<u>22,017,229</u>	<u>11,394,971</u>
