
**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 8, 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 August 8, 2016, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2016 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

Description

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 8, 2016

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

EXHIBIT INDEX

**Exhibit
Number**
99.1

Description
Press release issued by Agile Therapeutics, Inc. dated August 8, 2016.

Agile Therapeutics Reports Second Quarter 2016 Financial Results

Twirla® Clinical Trial Expected to Complete in Fourth Quarter 2016 and Resubmission Planned for First Half 2017; Cash Expected to Fund Operations Through the End of 2017

PRINCETON, New Jersey, August 8, 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 and six months ended June 30, 2016 and provided a corporate update for the second quarter 2016.

Second quarter 2016 and other recent corporate developments include:

- In June 2016, the Company received notice that the U.S. Patent and Trademark Office issued a patent with claims covering the formulation of a progestin-only transdermal patch containing levonorgestrel.
- In July 2016, the Company announced the appointment of Renee Selman as its new Chief Commercial Officer. Ms. Selman is a former senior executive at Johnson & Johnson who led the commercial launch of ORTHO EVRA®, one of the most successful contraceptive launches in the U.S. and the first ever contraceptive patch.
- In July 2016, the Company announced that it planned to begin clinical development of AG200-SP, an intended line extension of Twirla®, a once weekly contraceptive patch currently in Phase 3 development. The Company is preparing to conduct an initial Phase 2 clinical trial that will examine the use of AG200-SP in a novel regimen designed to allow women to experience shorter, lighter periods. The planned AG200-SP regimen will include the use of Twirla for three weeks followed by the use of a small patch in the fourth week of the woman's cycle. The initial Phase 2 clinical trial is designed to optimize the bleeding profile by delivering hormones beyond the typical 21-day regimen using a smaller lower-dose combination ethinyl/levonorgestrel patch in the fourth week of the woman's cycle.
- In July 2016, the Company announced the appointment of Seth H. Z. Fischer to the Company's Board of Directors. Mr. Fischer, who brings significant management and commercial experience, has more than three decades of healthcare experience in the pharmaceutical and medical device industry and currently serves as Chief Executive Officer and Director of Vivus, Inc., a publicly traded biopharmaceutical company.

"During the first half of this year, we believe we made significant progress on the execution of our business strategy to build a commercially competitive women's health franchise," stated Al Altomari, President and Chief Executive Officer of Agile. "Our primary focus continues to be on the SECURE trial, which we expect to complete in the fourth quarter of 2016. In addition, with the planned clinical development of our first line extension for Twirla, we believe we will be positioned to expand our market potential."

Second Quarter 2016 Financial Results

- **Cash and cash equivalents:** As of June 30, 2016, Agile had \$59.2 million of cash and cash equivalents compared to \$34.4 million of cash and cash equivalents as of December 31, 2015. Based on its current business plan, Agile believes its cash and cash equivalents will be sufficient to meet its operating requirements through the end of 2017.
- **Research and development (R&D) expenses:** R&D expenses were \$5.6 million for the quarter ended June 30, 2016, compared to \$6.2 million for the comparable period in 2015. The decrease in R&D expense was primarily due to decreased clinical site 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 June 30, 2016, compared to \$1.8 million for the comparable period in 2015. The increase in G&A expenses was primarily due to increased stock-based compensation expense associated with 2016 stock option grants as well as increased legal costs, search fees and consulting expense.
- **Net loss:** Net loss was \$8.4 million, or \$0.29 per basic share for the quarter ended June 30, 2016, compared to a net loss of \$8.5 million, or \$0.38 per basic share for the quarter ended June 30, 2015.
- **Shares Outstanding:** At June 30, 2016, Agile had 28,752,719 shares of common stock outstanding.

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)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,224	\$ 34,395
Prepaid expenses	2,073	3,690
Total current assets	61,297	38,085
Property and equipment, net	12,329	12,318
Other assets, long-term	18	18
Total assets	<u>\$ 73,644</u>	<u>\$ 50,421</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,270	\$ 5,040
Loan payable, current portion	5,568	2,336
Warrant liability	276	406
Total current liabilities	10,114	7,782
Loan payable, long-term	10,008	12,896
Stockholders' equity		
Common stock	3	2
Additional paid-in capital	233,982	194,468
Accumulated deficit	(180,463)	(164,727)
Total stockholders' equity	53,522	29,743
Total liabilities and stockholders' equity	<u>\$ 73,644</u>	<u>\$ 50,421</u>

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,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 5,577	\$ 6,168	\$ 10,505	\$ 11,546
General and administrative	2,264	1,813	4,316	3,413
Total operating expenses	7,841	7,981	14,821	14,959
Loss from operations	(7,841)	(7,981)	(14,821)	(14,959)
Interest expense, net	(515)	(546)	(1,045)	(971)
Change in fair value of warrants	(62)	41	130	(59)
Loss on extinguishment of debt	—	—	—	(1,036)
Loss before benefit from income taxes	(8,418)	(8,486)	(15,736)	(17,025)
Benefit from income taxes	—	—	—	—

Net loss	<u>\$</u>	<u>(8,418)</u>	<u>\$</u>	<u>(8,486)</u>	<u>\$</u>	<u>(15,736)</u>	<u>\$</u>	<u>(17,025)</u>
Net loss per common share:								
Basic and Diluted	<u>\$</u>	<u>(0.29)</u>	<u>\$</u>	<u>(0.38)</u>	<u>\$</u>	<u>(0.57)</u>	<u>\$</u>	<u>(0.78)</u>
Weighted-average shares outstanding:								
Basic and Diluted		<u>28,744,004</u>		<u>22,202,680</u>		<u>27,785,113</u>		<u>21,745,318</u>