
**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**

November 9, 2015

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 November 9, 2015, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2015 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 November 9, 2015.

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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: November 9, 2015

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

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EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated November 9, 2015.

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Agile Therapeutics Reports Third Quarter Financial Results

Completion of the SECURE Clinical Trial for Twirla® Planned for Second Half of 2016; Resubmission to the FDA Planned for the First Half of 2017

PRINCETON, New Jersey, November 9, 2015 - 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 nine months ended September 30, 2015 and provided a corporate update for the third quarter 2015.

Third quarter 2015 and other recent corporate developments include:

- In July 2015, the Company received notice that the U.S. Patent and Trademark Office issued Notices of Allowance for four patent applications with claims directed to novel transdermal contraceptive dosing regimens. The allowances of these patent applications provides the Company with an additional proprietary platform for the development of new products based on the Company's lead product candidate Twirla® (AG200-15).
- In October 2015, the Company announced completion of subject enrollment in its Phase 3 SECURE Clinical Trial for Twirla, its investigational combined hormonal contraceptive patch. The Company reported that the subject demographics enrolled are consistent with the Company's goal of a broadly representative subject population including fewer than twenty percent of subjects who are naïve to hormonal contraceptive products.

"We made significant progress in advancing our SECURE clinical trial during the third quarter of 2015 through the completion of subject enrollment," said Al Altomari, Chief Executive Officer and President of Agile. "As we continue to execute on our core strategy, we will have a strong focus on the continued execution of the SECURE trial while planning to manage our financial resources in order to achieve our objectives."

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2015, Agile had \$39.4 million of cash and cash equivalents compared to \$40.2 million of cash and cash equivalents as of December 31, 2014. Based on the current business plan, the Company believes its cash and cash equivalents will be sufficient to meet its operating requirements through the end of 2016. In addition to its existing cash and cash equivalents, 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 \$7.2 million for the quarter ended September 30, 2015, compared to \$4.6 million for the comparable period in 2014. The increase in R&D expense of \$2.6 million was primarily due to clinical research organization costs associated with the ongoing Phase 3 clinical trial for Twirla.
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- **General and administrative (G&A) expenses:** G&A expenses were \$1.8 million for the quarter ended September 30, 2015, compared to \$1.4 million for the comparable period in 2014. The increase in G&A expenses of \$0.4 million was primarily due to increased stock-based compensation expense associated with 2015 stock option grants.
 - **Net loss:** Net loss was \$9.4 million, or \$0.42 per basic share for the quarter ended September 30, 2015, compared to a net loss of \$6.4 million, or \$0.34 per basic share for the quarter ended September 30, 2014.
 - **Shares Outstanding:** At September 30, 2015, Agile had 22,292,167 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 and conduct of our clinical trial could be affected by the potential that 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.

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,404	\$ 40,182
Prepaid expenses	1,261	804
Total current assets	40,665	40,986
Property and equipment, net	12,320	12,046
Other assets, long-term	2,100	1,794
Total assets	<u>\$ 55,085</u>	<u>\$ 54,826</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,698	\$ 3,693
Loan payable, current portion	—	5,003
Warrant liability	251	296
Total current liabilities	6,949	8,992
Loan payable, long-term	15,390	9,828
Stockholders' equity		
Common stock	2	2
Additional paid-in capital	193,572	170,396
Accumulated deficit	(160,828)	(134,392)
Total stockholders' equity	32,746	36,006
Total liabilities and stockholders' equity	<u>\$ 55,085</u>	<u>\$ 54,826</u>

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 7,162	\$ 4,603	\$ 18,709	\$ 8,388
General and administrative	1,803	1,446	5,215	3,603
Total operating expenses	8,966	6,049	23,924	11,991
Loss from operations	(8,966)	(6,049)	(23,924)	(11,991)
Interest expense, net	(550)	(391)	(1,521)	(1,172)
Change in fair value of warrants	104	86	45	279
Loss on extinguishment of debt	—	—	(1,036)	—
Loss before benefit from income taxes	(9,411)	(6,353)	(26,436)	(12,885)
Benefit from income taxes	—	—	—	3,652
Net loss	<u>\$ (9,411)</u>	<u>\$ (6,353)</u>	<u>\$ (26,436)</u>	<u>\$ (9,232)</u>
Net loss per common share:				
Basic and Diluted	<u>\$ (0.42)</u>	<u>\$ (0.34)</u>	<u>\$ (1.21)</u>	<u>\$ (1.03)</u>
Weighted-average shares outstanding:				
Basic and Diluted	<u>22,272,777</u>	<u>18,592,968</u>	<u>21,923,070</u>	<u>8,967,324</u>