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 7, 2016
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** (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:

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))

Item 2.02 Results of Operations and Financial Condition

On November 7, 2016, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 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 Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated November 7, 2016.

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 7, 2016

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 November 7, 2016.

Exhibit 99.1

Agile Therapeutics Reports Third Quarter 2016 Financial Results and Announces Completion of Subject Visits for Twirla® Phase 3 SECURE Clinical Trial

Top-Line Data Expected in Early January 2017; Resubmission Planned for First Half 2017

Cash Expected to Fund Operations Through the End of 2017

PRINCETON, New Jersey, November 7, 2016 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's health specialty pharmaceutical company, today announced completion of all final subject visits for its Twirla® Phase 3 SECURE clinical trial, reported financial results for the three and nine months ended September 30, 2016, and provided a corporate update for the third quarter 2016.

"Completion of all subject visits in our SECURE clinical trial is a significant milestone in the development of Twirla," said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer of Agile. "We can now move forward with data verification and database lock activities, which we anticipate being completed by the end of December 2016. We will then proceed with initial data analysis and expect to announce top-line data in early January 2017. We believe we have conducted a well-run trial focused on quality and the key metrics the U.S. Food and Drug Administration (FDA) has indicated would be most important in their assessment of SECURE. We look forward to submitting a comprehensive package of reliable data that we believe can respond to the FDA's questions as well as establish the safety and efficacy profile for Twirla. We would like to thank our investigators and their staff, our partners and, most importantly, the women who participated in SECURE for helping us conduct such a rigorous study."

SECURE is a multicenter, single-arm, open-label Phase 3 clinical trial evaluating the safety, efficacy and tolerability of Twirla in 2032 healthy women aged 18 and over at 102 experienced investigative sites across the United States. The clinical trial was designed in consultation with the FDA in response to their 2013 complete response letter (CRL). The FDA recommended that the Company conduct a clinical trial that would address prior conduct and quality issues and demonstrate efficacy as measured by an acceptable pearl index and related confidence interval in a representative sample of U.S. women with respect to key demographic criteria including contraceptive user status, age, race, ethnicity, and body mass index (BMI). Twirla contains the active ingredients ethinyl estradiol and levonorgestrel, both of which have an established history of efficacy and safety in currently marketed low-dose combination oral contraceptives. The patch is intended to be applied once weekly for three weeks followed by a patch-free week, and is designed to promote user compliance.

Third quarter 2016 and other recent corporate developments include:

- In August 2016, the Company amended its loan agreement with Hercules Capital, Inc. The amendment, among other things, extends the period during which the Company can draw the second tranche of $8.5 million of its term loan until March 31, 2017 and also extends the interest-only payment period on its first tranche of the term loan to January 31, 2017.

- In October 2016, the Company's Board of Directors appointed Al Altomari, the Company's President and Chief Executive Officer, as Chairman of the Board and Abhijeet Lele as the Lead Independent Director of the Board.

"With the anticipated conclusion of our SECURE clinical trial, we will now increase our focus on the resubmission process," stated Al Altomari, Chairman and Chief Executive Officer of Agile. "We look forward to continuing our dialogue with the FDA as we prepare our CRL response and NDA resubmission, which is planned for the first half of 2017. We believe that making Twirla commercially available will begin to fill a strong need for innovative products in women's health."

Third Quarter 2016 Financial Results

- **Cash and cash equivalents:** As of September 30, 2016, Agile had $51.7 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 $4.9 million for the quarter ended September 30, 2016, compared to $7.2 million for the comparable period in 2015. The decrease in R&D expense was primarily due to decreased investigator and clinical site costs associated with the ongoing Phase 3 clinical trial for Twirla.

- **General and administrative (G&A) expenses:** G&A expenses were $2.2 million for the quarter ended September 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 $7.8 million, or $0.27 per basic share for the quarter ended September 30, 2016, compared to a net loss of $9.4 million, or $0.42 per basic share for the quarter ended September 30, 2015.

- **Shares Outstanding:** At September 30, 2016, Agile had 28,757,719 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, timelines for clinical trials and regulatory submissions 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, regulatory submissions and our ability to potentially commercialize our product candidates, could be affected by factors such as the identification of serious side effects or other safety issues, complications in the database lock process, completion of the analysis of the data takes longer than expected, unexpected issues raised by regulatory agencies in connection with our resubmission and the inherent risks of clinical development and the regulatory approval process; 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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 51,670	$ 34,395
Prepaid expenses	3,094	3,690
Total current assets	54,764	38,085
Property and equipment, net	12,330	12,318
Other assets, long-term	18	18
Total assets	$ 67,112	$ 50,421
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,644	$ 5,040
Loan payable, current portion	3,486	2,336
Warrant liability	238	406
Total current liabilities	8,368	7,782
Loan payable, long-term	12,077	12,896
Stockholders’ equity		
Common stock	3	2
Additional paid-in capital	234,931	194,468
Accumulated deficit	(188,267)	(164,727)
Total stockholders’ equity	46,667	29,743
Total liabilities and stockholders’ equity	$ 67,112	$ 50,421

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,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 4,911	$ 7,162	$ 15,415	$ 18,709
General and administrative	2,180	1,803	6,497	5,215
Total operating expenses	7,091	8,965	21,912	23,924

Loss from operations	(7,091)	(8,965)	(21,912)	(23,924)
Interest expense, net	(751)	(550)	(1,796)	(1,521)
Change in fair value of warrants	38	104	168	45
Loss on extinguishment of debt	—	—	—	(1,036)
Loss before benefit from income taxes	(7,804)	(9,411)	(23,540)	(26,436)
Benefit from income taxes	—	—	—	—
Net loss	$ (7,804)	$ (9,411)	$ (23,540)	$ (26,436)
Net loss per common share:				
Basic and Diluted	$ (0.27)	$ (0.42)	$ (0.84)	$ (1.21)
Weighted-average shares outstanding:				
Basic and Diluted	28,754,458	22,272,777	28,110,587	21,923,070