
**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, 2019

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, 2019, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2018 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, 2019.

EXHIBIT INDEX

Exhibit
Number

Description

99.1

[Press release issued by Agile Therapeutics, Inc. dated March 12, 2019.](#)

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, 2019

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

Agile Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

Cash Expected to Enable Company to Fund Operations into the Fourth Quarter of 2019

Company plans to resubmit Twirla NDA in second quarter of 2019

PRINCETON, New Jersey, March 12, 2019 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months and year ended December 31, 2018 and provided a corporate update.

Fourth quarter 2018 and other recent corporate developments:

Twirla® Update

- *Formal Dispute Resolution Ended:* As previously announced, in October 2018, the U.S. Food and Drug Administration's (FDA) Office of New Drugs (OND) formally denied the Company's formal dispute resolution (FDR) appeal and provided an alternative path forward for resubmission of the new drug application (NDA) for Twirla, the Company's lead product candidate. In its FDR decision, the OND recommended that the Company conduct a comparative wear study to evaluate whether Twirla demonstrates a generally similar adhesion performance to Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion.
- *Comparative Wear Trial Completed:* On February 11, 2019, the Company announced topline results of a comparative wear study of Twirla and Xulane®, which demonstrated that Twirla was statistically non-inferior to Xulane. The Company had previously reported that in its December 2018 meeting with FDA's Division of Bone, Reproductive and Urologic Products, (DBRUP), DBRUP agreed that Twirla would show adequate adhesion if it demonstrated statistical non-inferiority to Xulane in this study.
- *NDA Resubmission Plans:* The Company plans to resubmit its Twirla NDA in the second quarter of 2019. The planned resubmission is intended to be a complete response to the complete response letter the Company received from the FDA in December 2017 (2017 CRL) and will include the results from the comparative wear study, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL.

Financing Update

- On March 4, 2019, the Company completed the sale of approximately 8.4 million shares of common stock at \$0.93 per share to an institutional accredited investor through a private placement, resulting in gross proceeds of approximately \$7.8 million.

"We are pleased to have completed our private placement and appreciate the support from our new investor," said Al Altomari, Chairman and Chief Executive Officer of Agile. "We believe we now have the funding in place to execute our regulatory strategy to seek the approval of Twirla. We continue to believe that Twirla, if approved, will provide women with an important contraception option they do not currently have — a once-weekly contraceptive patch designed to deliver a low dose of estrogen."

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2018, Agile had \$7.8 million of cash and cash equivalents compared to \$35.9 million of cash and cash equivalents as of December 31, 2017. The Company believes
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its cash and cash equivalents as of December 31, 2018 along with the proceeds from its private placement completed in March 2019, will be sufficient to meet its projected operating requirements into the fourth quarter of 2019. The Company will require additional capital to fund operating needs for the remainder of the fourth quarter of 2019 and beyond, which will include, among other items, the completion of its commercial plan for Twirla, if approved, which primarily includes validation of the commercial manufacturing process and the commercial launch, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were \$1.9 million for the quarter ended December 31, 2018 and \$9.8 million for the year ended December 31, 2018, compared to \$2.7 million and \$14.4 million for the comparable periods in 2017. The decrease in R&D expenses was primarily due to a decrease in manufacturing and commercialization expenses reflecting reduced activity associated with the scale-up process and the on-going qualification process of the commercial manufacturing equipment primarily as a result of the receipt of the 2017 CRL.
- **General and administrative (G&A) expenses:** G&A expenses were \$1.6 million for the quarter ended December 31, 2018 and \$8.7 million for the year ended December 31, 2018, compared to \$3.3 million and \$12.4 million for the comparable periods in 2017. The decrease in G&A expenses was primarily due to the suspension of pre-commercialization activities as a result of the receipt of the 2017 CRL.
- **Net loss:** Net loss was \$3.8 million, or \$0.11 per share, for the quarter ended December 31, 2018, compared to a net loss of \$6.2 million, or \$0.18 per share, for the quarter ended December 31, 2017. Net loss for the year ended December 31, 2018 was \$19.8 million, or \$0.58 per share, compared to a net loss of \$28.3 million or \$0.91 per share for the year ended December 31, 2017.
- **Shares Outstanding:** At December 31, 2018, Agile had 34,377,329 shares of common stock outstanding.

About Twirla® (AG200-15)

Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational low-dose, once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. Agile received a complete response letter (“CRL”) from the FDA in December 2017 relating to the New Drug Application (“NDA”) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form. The Company plans to resubmit the Twirla NDA in the second quarter of 2019.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

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 an investigational low-dose, non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company’s website.

Forward-Looking Statement

Certain information contained in this press release includes “forward-looking statements”, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as

amended, 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,” “likely,” “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, including statements regarding statements regarding the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond the fourth quarter of 2019, 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, our expectations about Twirla and its NDA, and the use of the net proceeds of our recently completed private placement. 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. These forward looking statements are subject to risks and uncertainties including risks related to our available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern, our ability to adequately and timely respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our data do not support resubmission or approval of Twirla NDA and requires us to conduct additional studies to address the concerns raised in the 2017 CRL, our ability to resubmit the Twirla NDA and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain, our ability to obtain a favorable Advisory Committee vote in the likely event the FDA requires an Advisory Committee to review the benefit and risk profile of Twirla, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing, our third-party manufacturer, Corium International, Inc.’s (Corium) inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium’s manufacturing facility and to pass a likely FDA pre-approval inspection, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, our ability to retain key employees, regulatory and legislative developments in the United States and foreign countries, our plans to commercialize Twirla and develop our other potential product candidates, the size and growth of the potential markets for our product candidates and our ability to serve those markets, the rate and degree of market acceptance of any of our product candidates, our ability to obtain and maintain intellectual property protection for our product candidates, the successful development of our sales and marketing capabilities, our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, our ability to successfully implement our strategy and the other risks set forth 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. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. 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: Investor Relations — 609-683-1880

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,851	\$ 35,952
Prepaid expenses	607	762
Total current assets	8,458	36,714
Property and equipment, net	13,916	13,863
Other assets	18	18
Total assets	<u>\$ 22,392</u>	<u>\$ 50,595</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,218	\$ 3,636
Loan payable, current portion	—	10,607
Warrant liability	—	29
Total liabilities	2,218	14,272
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	261,722	258,092
Accumulated deficit	(241,551)	(221,772)
Total stockholders' equity	20,174	36,323
Total liabilities and stockholders' equity	<u>\$ 22,392</u>	<u>\$ 50,595</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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 1,856	\$ 2,734	\$ 9,777	\$ 14,428
General and administrative	1,567	3,254	8,739	12,383
Restructuring costs	304	—	1,019	—
Total operating expenses	<u>3,727</u>	<u>5,988</u>	<u>19,535</u>	<u>26,811</u>
Loss from operations	(3,727)	(5,988)	(19,535)	(26,811)
Other income (expense)				
Interest expense	(160)	(409)	(1,116)	(1,918)
Interest income	77	95	366	282
Change in fair value of warrants	—	62	29	143
Loss before benefit from income taxes	<u>(3,810)</u>	<u>(6,240)</u>	<u>(20,256)</u>	<u>(28,304)</u>
Benefit from income taxes	—	—	477	—
Net loss	<u>\$ (3,810)</u>	<u>\$ (6,240)</u>	<u>\$ (19,779)</u>	<u>\$ (28,304)</u>
Net loss per share - basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.18)</u>	<u>\$ (0.58)</u>	<u>\$ (0.91)</u>
Weighted-average shares outstanding — basic and diluted	<u>34,377,329</u>	<u>34,183,772</u>	<u>34,315,931</u>	<u>30,940,831</u>