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

May 15, 2018
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**	**08540**
(Address of principal executive offices)	(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))

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 x

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. x

Item 8.01. Other Events.

On May 18, 2018, Agile Therapeutics, Inc. (the "Company") issued a press release announcing the results of the Company's April 16, 2018 Type A meeting (the "Type A Meeting") with the U.S. Food and Drug Administration (the "FDA"). The Company had the Type A Meeting to discuss the complete response letter dated December 21, 2017 (the "CRL") that the FDA issued in connection with the June 26, 2017 New Drug Application ("NDA") resubmission for the Company's investigational low dose, non-daily combination hormonal contraceptive patch, Twirla (AG200-15). The Company received the final meeting minutes from the FDA on May 15, 2018.

In the minutes, the FDA informed the Company that it continues to have significant concerns regarding the adhesion of Twirla, which the FDA believes cannot be addressed through the Company's proposed patient compliance programs. The FDA recommended that the Company should address the Twirla adhesion properties by reformulating the transdermal system; conducting a formal adhesion study with the new formulation; and demonstrating bioequivalence to the data and information for the original formulation. The FDA advised the Company that, after the Company satisfies the FDA's questions on adhesion and adequately bridges to the findings in the SECURE Phase 3 trial, it anticipates discussing the safety and efficacy of Twirla at an advisory committee meeting to obtain input on whether the benefits outweigh the risks. In the absence of a finding of bioequivalence, the Company would need to conduct a new Phase 3 study with the new formulation. Finally, the FDA provided guidance on a path forward for addressing manufacturing issues related to Twirla, which path is largely based on the materials the Company had previously submitted in December 2017.

The Company will continue to evaluate all of its options on next steps and expects it will pursue formal dispute resolution. The Company will provide an update when it moves forward. In the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, the Company disclosed that it believes its cash and cash equivalents as of March 31, 2018, will be sufficient to meet its operating requirements through the end of 2018. In light of feedback from the FDA, the Company is re-evaluating its business plan to identify ways to extend its ability to fund its operations even further.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated May 18, 2018.

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: May 18, 2018

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

FOR IMMEDIATE RELEASE

Agile Therapeutics, Inc. Provides Regulatory Update on Twirla® (AG200-15) for the Prevention of Pregnancy

PRINCETON, N.J., May 18, 2018 — Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today announced the content of the official minutes from its Type A meeting with the U.S. Food and Drug Administration (FDA) held on April 16, 2018 to discuss the complete response letter (CRL) issued by the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla (AG200-15), the Company's investigational low-dose, non-daily, combination hormonal contraceptive patch. In the CRL, the FDA informed the Company that the Twirla NDA could not be approved due to deficiencies related to the manufacturing process and facility for Twirla, and because of questions the FDA had on the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results.

In the official minutes, the FDA informed the Company that it continues to have significant concerns regarding the adhesion of Twirla, which the FDA believes cannot be addressed through the Company's proposed patient compliance programs, and that the Company needed to address the Twirla adhesion properties by reformulating the transdermal system and conducting a formal adhesion study with the new formulation. The FDA also informed the Company that it would need to demonstrate bioequivalence to the data and information for the original formulation. The FDA advised the Company that after the Company satisfies the FDA's questions on adhesion and adequately bridges to the findings in the SECURE Phase 3 trial, it anticipates discussing the safety and efficacy of Twirla at an advisory committee meeting to obtain input on whether the benefits outweigh the risks. In the absence of a finding of bioequivalence, the Company would need to conduct a new Phase 3 study with the new formulation. Finally, the FDA provided guidance on the path forward for addressing manufacturing issues related to Twirla, which path is largely based on the materials the Company had previously submitted in December 2017. To the extent that the Company reformulates Twirla, it may create the need for additional manufacturing work and review by the FDA.

"We believe we had a constructive meeting with the FDA, however, we disagree with the FDA's conclusions on the adhesion of Twirla and our patient compliance programs. We believe we have demonstrated an adhesion profile for Twirla that supports approval based on extensive data from our Phase 2 studies, including an extreme conditions trial, and our three Phase 3 trials. We also believe that we have planned compliance and education programs that can address the issues raised by the FDA and will support patient use of the product once it is approved. While we will continue to evaluate all of our options on next steps, we expect we will

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pursue formal dispute resolution. We will provide an update when we move forward," said Al Altomari, Chairman and Chief Executive Officer, Agile Therapeutics. "In light of the feedback from the FDA, we also are re-evaluating our business plan to identify ways to extend our ability to fund the Company's operations," concluded Mr. Altomari.

Company to Host Conference Call

Agile Therapeutics will host a conference call on May 18, 2018 at 8:00 a.m. Eastern Time to discuss the Company's regulatory update. A question and answer session will follow Agile Therapeutics' remarks. To participate on the live call, please dial (844) 413-1773 (domestic) or (678) 865-8976 (international), and provide the conference ID number: 5858819.

A live audio webcast of the call will be available via the "Investor Relations" page of the Agile Therapeutics website, www.agiletherapeutics.com. Please log on through Agile Therapeutics' website approximately 10 minutes prior to the scheduled start time. A replay of the webcast will be archived on Agile Therapeutics' website for 60 days following the call.

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational once-weekly prescription contraceptive patch. AG200-15 is a 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.

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® (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15, is an investigational 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.

Follow Agile on Linked In and Twitter: @AgileTher.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" 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.

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. Our statements about our ability to adequately and timely respond to the deficiencies in the CRL issued by the FDA in December 2017 may be affected by whether any such response will be accepted by the FDA, our ability to address the FDA's concerns regarding Twirla raised in the Type A meeting minutes issued by the FDA in May 2018, our ability to either succeed in our discussions with the FDA that a reformulation of Twirla is not necessary, or if we are unsuccessful, our ability to develop a reformulation that will address the FDA's concerns, if we are required to reformulate Twirla, our ability to successfully complete an additional adhesion study and bioequivalence study, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA; our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute our operational and budget plans, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond 2018, 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, and unforeseen events in our clinical and manufacturing development plans; our statements about the potential commercial opportunity could be affected by potential labeling restrictions, 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 our 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, Inc.

Contact:

Investor Relations
Agile Therapeutics
609-683-1880

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