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

December 21, 2017
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))

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 December 22, 2017, Agile Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) dated December 21, 2017 in response to the New Drug Application (NDA) resubmission for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15).

The Company also hosted a conference call on December 22, 2017, at 8:00 a.m. Eastern Time to discuss the regulatory update.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and a copy of the Company's script to the conference call is attached hereto as Exhibit 99.2, and each 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 December 22, 2017.
99.2	Script to Conference Call held on December 22, 2017

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: December 22, 2017

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

Exhibit 99.1

Agile Therapeutics, Inc. Receives a Complete Response Letter from the FDA for Twirla® (AG200-15) for the Prevention of Pregnancy

PRINCETON, N.J., December 22, 2017 — Agile Therapeutics, Inc., (NASDAQ: AGRX), a women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) in response to the New Drug Application (NDA) resubmission for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15). The resubmission of the NDA, which is seeking approval for Twirla was accepted for review earlier this year. The Prescription Drug User Fee Act (PDUFA) goal date was December 26, 2017. The CRL states that the FDA has determined that it cannot approve the NDA in its present form.

The CRL identifies deficiencies relating to quality adhesion test methods. The CRL also noted that observations identified during an inspection of a facility of the Company's third-party manufacturer, Corium International Inc., (Corium), for the Twirla NDA must be resolved. Lastly, the CRL questions the in vivo adhesion properties of Twirla and their potential relationship to the SECURE phase 3 clinical trial results. The CRL contains recommendations for developing manufacturing in-process tests for ensuring the quality and in vivo adhesion of the commercial scale product as well as the finished drug specifications and release test method for adhesion. The CRL also recommends that the Company assess the in vivo adhesion properties demonstrated in the SECURE clinical trial. Finally, the CRL recommends that the Company address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. The CRL does not identify any specific issues relating to the safety of Twirla.

During the review cycle, the Company submitted an amendment to the NDA in response to an information request from the FDA on the issues related to quality adhesion test methods cited in the CRL. In addition, Corium also provided the FDA responses addressing each of the observations made during the FDA's facility inspection on November 20, 2017 and December 1, 2017. The CRL acknowledges receipt of the Company's NDA amendment submitted on December 1, 2017, and states that the amendment was not reviewed prior to the FDA's action. The FDA indicated that applicable sections of the amendment submitted by Agile could be incorporated when responding to deficiencies noted in the CRL.

"We are clearly disappointed, and we are evaluating the FDA's response," said Al Altomari, chairman and chief executive officer, Agile Therapeutics. "We intend to request a meeting with the FDA as soon as possible to discuss the points raised in the CRL and discuss a path to approval for Twirla. We will work closely with the FDA to address the points raised in the CRL as quickly as possible."

Company to Host Conference Call

Agile Therapeutics will host a conference call on December 22, 2017 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: 3979609.

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 a 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 while optimizing patch adhesion and comfort for the patient. 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 the Company's regulatory submissions. 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 beliefs and expectations of our management team that involves 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 Twirla CRL issued by the FDA may be affected by whether any such response will be accepted by the FDA, our ability and timing to resubmit the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, the FDA may require additional studies to address the concerns raised in the CRL (for example, if it is determined that the product adhesion concerns are due to the design or formulation of the drug product, the FDA may recommend that we design a new transdermal system and conduct another clinical trial with the new transdermal system in a U.S. population), or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA: our statements about the results of our clinical trial could be affected by the potential that there are changes in the interpretation of the data by the FDA (for example, the FDA continues to question the number of pregnancies included in our results and they may adjudicate additional pregnancies); our statements about the potential commercial opportunity

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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 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, Inc.

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Agile Therapeutics Regulatory Update Conference Call Script

Conference Call Operator

Good day, ladies and gentlemen and welcome to the Agile Therapeutics regulatory update conference call and webcast.

All participants are currently in listen-only mode. Following the prepared remarks, we will open the lines for a question-and-answer session. As a reminder, this conference call may be recorded.

At this time, I will turn the call over to Geoff Gilmore, General Counsel of Agile Therapeutics.

GEOFF GILMORE, GENERAL COUNSEL

Geoff Gilmore

Thank you, Operator, and good morning, everyone.

The press release announcing the regulatory update for Agile's lead product candidate, Twirla®, also known as AG200-15, an investigative once-weekly prescription contraceptive patch, was issued on December 22, 2017. For those of you who have not yet seen it, you will find it posted in the "Investors" section of our website at www.agiletherapeutics.com.

Joining us on our call today from Agile are Al Altomari, our Chairman and Chief Executive Officer, Dr. Elizabeth Garner, our Chief Medical Officer; Renee Selman, our Chief Commercial Officer; and Scott Coiante, our Chief Financial Officer.

Before we begin our prepared remarks, I would like to remind you that various statements we make during this call about the Company's business, clinical and product development, regulatory strategy and plans, and objective for Agile's future operations, are considered forward-looking statements within the meaning of the federal securities laws. The Company cautions that these

forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time. Further information on the factors and risks that could affect our business, financial conditions and results of operations, including those mentioned in the forward-looking statements, are contained in Agile Therapeutics' filings with the U.S. Securities and Exchange Commission which are available at www.sec.gov. These forward-looking statements are based on information available to Agile today, and we assume no obligation to update statements as circumstances change.

An audio recording and webcast replay for today's conference call will also be available online in the "Investors" section of our website. For the benefit of those who may be listening to the replay or archived webcast, this call was held and recorded on December 22, 2017.

At this time, I would like to turn the call over to Al Altomari.

Al Altomari, Chairman and Chief Executive Officer

Al Altomari

Thank you Geoff.

Good morning everyone.

Clearly, we are disappointed with getting a CRL.

In our Press Release today we described three deficiencies or areas of concern in the CRL:

- First, the quality adhesion test methods
- Second, observations identified during an inspection of a facility of our third-party manufacturer, Corium International
- Lastly, questions relating to our in-vivo adhesion properties and their potential relationship to the SECURE phase 3 clinical trial results

I will talk about the first two deficiencies, then talk about our cash position. I will then ask Dr. Beth Garner to address the clinical side of the CRL and then conclude with our planned path forward. After Beth's remarks we will take questions.

Let me describe the quality adhesion test methods that were cited in the CRL.

The first test method has to do with tack. Tack is measured by touching the adhesive side of the patch with a probe.

The second test method has to do with adhesion. In this test a patch is placed on steel and the computer measures the adhesion as the patch is mechanically pulled off the steel.

In an information request we received in November, the FDA asked questions about tack and adhesion, and in the case of our adhesion test method they suggested we redevelop that method. Agile submitted an amendment to the NDA on December 1st addressing all of the FDA's questions. The amendment also included a new test method for adhesion that we qualified. It's worth mentioning, we followed the FDA recommendations on how to develop a new adhesion method. In summary, we believe our amendment on December 1st should address this deficiency.

The second deficiency was identified during a general inspection of Corium which also included Twirla. In conjunction with this inspection, Corium received a 483. The Twirla 483 observations were related again to tack and adhesion test methods and were consistent with the information request I just mentioned. Corium answered the 483 in a timely fashion.

In summary, we believe both manufacturing related deficiencies have been addressed in the Agile amendment submitted on December 1st and the Corium 483 responses submitted on November 20th and December 1st. As we mentioned in our Press Release, the CRL acknowledges receipt of the Agile December 1, 2017 NDA amendment and states that the amendment was not reviewed prior to the FDA's action.

I would like to provide you an overview of our cash position. In our third quarter 2017 financial results release, we stated that we expected our current cash would last into the second quarter of 2018 based on our then current business plan. We have now postponed all the major launch activities until we meet with the FDA. In short, we would expect the current cash to now last past the second quarter. We will update our cash guidance more specifically after the FDA meeting.

I would like to now ask Dr. Beth Garner to summarize the clinical side of the CRL and talk about our path forward.

Elizabeth Garner, Senior Vice President and Chief Medical Officer

Beth Garner

The FDA stated in the CRL, and we agree, that adhesion of the product to skin is critical for its safe and effective use. Following their points regarding quality adhesion testing methods, the FDA raised some questions as to whether adhesion issues may have contributed, at least in part, to any of the clinical trial results, specifically efficacy and bleeding. We believe the answer to this question is no, and that our robust clinical data support this conclusion; we also believe that to address this question for the FDA we may need to provide some additional analyses of the data, as well as additional context around how our adhesion data were collected. Finally, the CRL recommends that the Company address the implications of clinical trial subject patch compliance and the withdrawal and dropout rates. We will need to meet with the FDA to understand this issue more clearly. Finally, at the present time we do not believe that additional clinical trial work will be required.

With regard to safety, the FDA stated in the CRL that the profile of Twirla with respect to the known serious risks of hormonal contraception, including thromboembolic events, appears to be similar to that of other combined hormonal contraceptives.

We fully believe that the issues identified in this CRL can be addressed, and as Al stated, we will be actively engaging with the FDA to address these issues as quickly as possible.

At this time, I would like to turn the call back to Al.

Al Altomari, Chairman and Chief Executive Officer

Al Altomari

Thanks Beth. In conclusion, we intend to request a meeting with the FDA as quickly as possible. The goal of that meeting is to understand FDA's questions on the approvability of Twirla and discuss a path forward for approval. We will provide an update on that meeting once we receive the final meeting minutes.

Thank you again for your interest and support of Agile Therapeutics. Operator you can now open the line for questions.

OPERATOR

OPERATOR

Thank you. At this time the lines are open for questions.

The first caller is…..

At the end of Questions and Answer session, the Operator will end the call.

There are no more questions and this will conclude today's call. Thank you for joining us.

The End