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 17, 2019
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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

Item 8.01. Other Events

On May 17, 2019, Agile Therapeutics, Inc. ("Agile") announced it has resubmitted to the U.S. Food and Drug Administration ("FDA") the New Drug Application ("NDA") for its lead product candidate, Twirla®, an investigational low-dose combined hormonal contraceptive patch (AG200-15). Agile resubmitted the NDA in response to a December 2017 Complete Response Letter ("CRL") from the FDA, which identified deficiencies relating to (i) quality control adhesion test methods for the Twirla manufacturing process, (ii) observations identified during an inspection of a facility of our third-party manufacturer for the Twirla NDA that must be resolved, and (iii) questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results. The resubmitted NDA includes the results from a comparative wear study that was conducted at the request of the FDA to address the FDA's questions on *in vivo* adhesion, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL.

A copy of Agile'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	Agile Therapeutics, Inc. Press Release dated May 17, 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: May 17, 2019

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

Exhibit 99.1

Agile Therapeutics Resubmits New Drug Application (NDA) for its Transdermal Low-Dose Contraceptive Patch, Twirla®

PRINCETON, NJ, **May 17, 2019** — Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced it has resubmitted to the U.S. Food and Drug Administration (FDA) the NDA for its lead product candidate, Twirla®, an investigational low-dose combined hormonal contraceptive patch (AG200-15). Agile resubmitted the NDA in response to a December 2017 Complete Response Letter (CRL) from the FDA, which identified deficiencies relating to (i) quality control adhesion test methods for the Twirla manufacturing process, (ii) observations identified during an inspection of a facility of our third-party manufacturer for the Twirla NDA that must be resolved, and (iii) questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the SECURE clinical trial results. The resubmitted NDA includes the results from a comparative wear study that was conducted at the request of the FDA to address the FDA's questions on *in vivo* adhesion, additional information on the Company's manufacturing process, and other analyses responding to the 2017 CRL.

"We have resubmitted our NDA for Twirla as planned and look forward to working with the FDA during the review process," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Our achievement of this milestone reflects our commitment to broadening the available contraceptive treatment options for today's women by offering an option to women seeking methods best suited to their needs and lifestyle. We expect the FDA to acknowledge our submission as a complete response in approximately thirty days, and at the same time provide us with a Prescription Drug User Fee Act (PDUFA) date that we anticipate will be based on a six-month review."

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 for Twirla. 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 the FDA's acknowledgement of the resubmission of the Twirla NDA as a complete response, the timing of such acknowledgement and our expectations regarding the receipt of a PDUFA date and the timing of such date. 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 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 resubmitted NDA is not a complete response and refuses to review the NDA, or that our data do not support resubmission or approval of Twirla NDA and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the 2017 CRL, our ability to obtain and maintain regulatory approval of our product candidates, 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, 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, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for our product candidates, 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, 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