

AGILE THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 06/27/17 for the Period Ending 06/27/17

Address	101 POOR FARM ROAD PRINCETON, NJ 08540-1715
Telephone	609-683-1880
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Sector	Healthcare
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**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**

June 27, 2017

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 8.01. Other Events.

On June 27, 2017, 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 February 2013 Complete Response Letter (“CRL”) from the FDA, which recommended Agile conduct a new clinical trial and provide additional information on the manufacturing process for Twirla. The resubmitted NDA includes efficacy and safety data from the new Phase 3 clinical trial (also known as the SECURE trial), the requested manufacturing information, and a summary response to the 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	Press release issued by Agile Therapeutics, Inc. dated June 27, 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: June 27, 2017

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 June 27, 2017.

Agile Therapeutics Resubmits New Drug Application (NDA) for its Transdermal Contraceptive Patch, Twirla[®]

PRINCETON, NJ , June 27, 2017 — 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 February 2013 Complete Response Letter (CRL) from the FDA, which recommended that Agile conduct a new clinical trial and provide additional information on the manufacturing process for Twirla. The resubmitted NDA includes efficacy and safety data from the new Phase 3 clinical trial (also known as the SECURE trial), the requested manufacturing information, and a summary response to the 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 changing the paradigm of available contraceptive treatment options for today’s women and brings us one step closer to commercializing our low-dose contraceptive patch and offering an option to women seeking novel methods best suited to their needs and lifestyle. Once the FDA has acknowledged our submission as a complete response, we expect to receive 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 a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. 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 adhesion and patient wearability. 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 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 the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we may describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will negatively impact acceptance, review and approval of Twirla by the FDA; the FDA may delay its review longer than we expect; and 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

Investor Relations Contact:

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