

AGILE THERAPEUTICS INC
Form 8-K
July 28, 2017

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

July 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.)

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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 July 27, 2017, Agile Therapeutics, Inc. (Agile) announced that it had received a letter from the U.S. Food and Drug Administration (FDA) acknowledging that the resubmission of the the New Drug Application (NDA) for its lead product candidate, Twirla®, an investigational low-dose combined hormonal contraceptive patch (AG200-15), was a complete response to a February 2013 Complete Response Letter (CRL) from the FDA. The FDA established December 26, 2017 as the target Prescription Drug User Fee Act (PDUFA) goal date.

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 July 27, 2017. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: July 28, 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 July 27, 2017. |