

AGILE THERAPEUTICS INC
Form 8-K
July 13, 2016

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 12, 2016

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:

- 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))
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Item 8.01. Other Events.

On July 12, 2016, Agile Therapeutics, Inc. (Agile) issued a press release announcing that preparations are underway for an initial Phase 2 clinical trial of a novel contraceptive regimen, which will begin the development of its pipeline beyond its current lead product candidate, Twirla®, a once weekly contraceptive patch currently in Phase 3 development. The planned Phase 2 clinical trial will examine the use of Twirla in an innovative regimen designed to allow women to experience shorter, lighter periods, using a smaller lower dose combination ethinyl estradiol/levonorgestrel patch (SmP). Agile has started preparations for the trial and expects to initiate dosing in the first quarter of 2017. Agile also announced that it has plans to develop an extended cycle regimen for Twirla (AG200-ER) that may also utilize the SmP with the goal of allowing women to have fewer periods each year.

On July 12, 2016, Agile also updated its corporate presentation that it intends to use in connection with presentations at conferences and meetings with investors. The updates include the information on its pipeline announced in the press release referenced above and the appointment of a new chief commercial officer, which was previously announced.

Copies of Agile s press release and presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are 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 July 12, 2016. |
| 99.2 | Agile Therapeutics, Inc. Presentation. |

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: July 13, 2016

| | |
|--------|---------------------------------------|
| By: | /s/ Alfred Altomari |
| Name: | Alfred Altomari |
| Title: | President and Chief Executive Officer |