

AGILE THERAPEUTICS INC
Form 8-K
November 03, 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

October 31, 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 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 October 31, 2017, the Company announced additional data from its Phase 3 SECURE trial of Twirla® (AG200-15), an investigational, once-weekly, low-dose hormonal contraceptive patch, which showed women experienced mean decreases in length of bleeding and spotting episodes. These data were presented during an oral presentation by Anita Nelson, MD, Professor and Chair, Obstetrics and Gynecology, College of Osteopathic Medicine of the Pacific, and Co-Principal Investigator of the Agile Therapeutics, Inc., SECURE Phase 3 clinical trial, at the American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo 2017 in San Antonio, Texas, and the abstract was published in *Fertility and Sterility*.

The presentation reported, among other items, that over 12 months, women on Twirla reported a gradual decrease in the mean total number of bleeding and/or spotting episodes from 6.0 to 4.9 days from cycles two through 13. Scheduled bleeding, or withdrawal bleeding during the patch-free week, decreased from 4.7 days at cycle two to 4.1 days at the end of the trial. The mean number of days of unscheduled bleeding, or breakthrough bleeding, decreased from 6.3 to 5.2 from cycle two through 13. While the duration of scheduled and unscheduled bleeding decreased, the mean number of episodes were consistent during the trial. Only 2.2% of women discontinued from the trial due to bleeding-related adverse events. presented data which showed women experienced mean decreases in length of bleeding and spotting episodes.

SECURE was a Phase 3, one-year, multicenter, single-arm, open-label trial that evaluated the safety, efficacy and tolerability of Twirla in 2032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. Agile announced top-line results of the SECURE clinical trial in January 2017. The Company's new drug application (NDA) for Twirla is currently under review by the U.S. Food and Drug Administration with a target Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2017.

Copies of the press release and presentation are attached hereto as Exhibit 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 | <u>Agile Therapeutics, Inc. Press Release dated October 31, 2017.</u> |
| 99.2 | <u>Agile Therapeutics, Inc. Presentation dated October 31, 2017.</u> |

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: November 3, 2017

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