

AGILE THERAPEUTICS INC
Form 8-K
October 24, 2018

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 24, 2018

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.)

Edgar Filing: AGILE THERAPEUTICS INC - Form 8-K

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 24, 2018 Agile Therapeutics, Inc. (Agile) a women s healthcare company, announced an oral presentation regarding predictors of pregnancy in the Phase 3 SECURE study of the investigational low-dose, once-weekly contraceptive patch, AG200-15 (Twirla®). Thomas D. Kimble, MD, Associate Dean and Assistant Professor of Obstetrics and Gynecology at Eastern Virginia Medical School, presented the new analyses at the North American Forum on Family Planning (NAFFP) on October 20, 2018 in New Orleans, Louisiana. The presentation, entitled *Body Mass Index and Weight are Predictors of Pregnancy in a Phase 3 Multicenter Contraceptive Efficacy Study of AG200-15, a Low-Dose Combination Hormonal Contraceptive Patch*, included detailed findings of statistical modeling performed to identify variables predictive of pregnancy in the SECURE study. The abstract is published in the October 2018 issue of *Contraception*.

The SECURE clinical trial was designed to evaluate the efficacy, safety, and tolerability of AG200-15, also known as Twirla (levonorgestrel/ethinyl estradiol), in a representative population of women seeking birth control. SECURE was a 1-year, multicenter, single-arm, open-label trial in 2032 healthy women aged 18 and over, at 102 experienced investigative sites across the United States.

Copies of Agile s press release, slides from Agile s presentation, and the abstract are attached hereto as Exhibits 99.1, 99.2, and 99.3 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 24, 2018</u>
99.2	<u>Agile Therapeutics, Inc. Oral Presentation Slides</u>
99.3	<u>Agile Therapeutics, Inc. Abstract</u>

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: October 24, 2018

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