

AGILE THERAPEUTICS INC
Form 8-K
October 19, 2015

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 19, 2015

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)).
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Item 8.01. Other Events.

On October 19, 2015, Agile Therapeutics, Inc. (Agile) issued a press release announcing that it had completed enrollment in its ongoing single-arm, open-label Twirla® Phase 3 SECURE clinical trial. The Company expects to complete the trial of over 2,000 subjects in the second half of 2016, and to submit its response to FDA's complete response letter in the first half of 2017. The Company announced that the subject demographics are consistent with its goals of a broadly representative patient population and fewer than twenty percent of subjects who are naïve to hormonal contraceptive products. The SECURE study is a multicenter Phase 3 clinical trial of Twirla (AG200-15) of over 2,000 female subjects who will receive treatment for up to one year. The clinical trial will assess the effectiveness of the patch in preventing pregnancy using the Pearl Index as the primary contraceptive efficacy measure. Safety and tolerability will also be evaluated.

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	Agile Therapeutics, Inc. Press Release dated October 19, 2015 relating to the completion of enrollment in the SECURE Study.

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: October 19, 2015

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