

**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.)

**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)).

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

Agile Therapeutics Announces Completion of Patient Enrollment in Twirla® Phase 3 SECURE Clinical Trial

Company Plans to Complete Clinical Trial in the Second Half of 2016 and File its Resubmission to the FDA in First Half of 2017

Princeton, New Jersey, October 19, 2015 — Agile Therapeutics, Inc. (Nasdaq: AGRX) a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today announced that it has reached full enrollment in its ongoing Phase 3 SECURE clinical trial of Twirla® (AG200-15), its investigational combined hormonal contraceptive patch. The Company expects to complete the trial of over 2,000 subjects in the second half of 2016.

"Reaching full enrollment in the SECURE clinical trial is a major accomplishment for Agile and all those who have been involved in our Twirla program. Our clinical sites demonstrated their commitment to quality throughout this important process of subject selection," stated Elizabeth Garner, M.D., M.P.H., Chief Medical Officer of Agile. "The patient demographics are consistent with our goals of a broadly representative patient population and fewer than twenty percent of subjects who are naïve to hormonal contraceptive products. Together with our partners and investigators, we now look forward to executing on this final, 12-month phase of the trial with continued focus on trial conduct and rigorous oversight, utilizing our technology platforms to support subject compliance and retention while minimizing loss to follow-up, all aimed at providing a high quality data package at the end of the trial."

The SECURE trial is a multicenter, single-arm, open-label Phase 3 clinical trial in which healthy women 18 and over will receive treatment with the investigational patch 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. Twirla contains the active ingredients ethinyl estradiol and levonorgestrel, both of which have an established history of efficacy and safety in currently marketed low-dose combination oral contraceptives. The patch is applied once weekly for three weeks followed by a patch-free week, and is designed to promote user compliance.

"We are very pleased with having achieved this critical milestone for the Twirla development program. We look forward to the results from the trial and we plan to submit our response to FDA's complete response letter in the first half of 2017," said Al Altomari, President and Chief Executive Officer of Agile. "Twirla represents an important new contraceptive innovation for women and the potential to be the first low-dose combined hormonal contraceptive patch."

Additional information on the SECURE clinical trial is available at www.clinicaltrials.gov.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over

currently available patches and is intended to optimize patch adherence and patient acceptability. For more information, please visit the company website at www.agiletherapeutics.com. The company may occasionally disseminate material, nonpublic information on the company website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's, projected timeline for clinical trials and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current expectations that involve risks, potential changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, our statements about the timing and conduct of our clinical trial could be affected by the potential that we experience difficulty in enrolling subjects, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Agile Therapeutics

Contact: Mary Coleman — 609-356-1921
