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	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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:

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))

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	Agile Therapeutics, Inc. Press Release dated October 24, 2018
99.2	Agile Therapeutics, Inc. Oral Presentation Slides
99.3	Agile Therapeutics, Inc. Abstract

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

Exhibit 99.1

Agile Therapeutics, Inc. Presents Additional Analyses of AG200-15 (Twirla®) Phase 3 SECURE Study Results at the 2018 North American Forum on Family Planning (NAFFP)

PRINCETON, N.J., October 24, 2018 — Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today 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), "The Forum", on October 20, 2018 in New Orleans, LA.

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 Phase 3 SECURE study was a multicenter, single-arm, open-label, 13 cycle trial designed to evaluate the efficacy, safety, and tolerability of AG200-15, also known as Twirla, in 2032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. The SECURE study included a number of stringent design elements, including exclusion of treatment cycles for use of back-up contraception and for lack of sexual activity. The study also had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse patient population in order to allow efficacy to be assessed across different, real-world groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with a high BMI, who have frequently been underrepresented in past contraceptive studies.

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. Agile received a complete response letter (CRL) from the FDA on December 21, 2017 relating to the New Drug Application (NDA) for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the FDA had on the in vivo adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. The FDA provided a path forward for resubmitting the Twirla NDA and suggested the Company conduct a comparative wear study to evaluate whether Twirla demonstrates generally similar adhesion performance to Xulane®. The Company plans to meet with the FDA to gain agreement on the specific design and success criteria for a wear study as soon as possible. The Company believes the FDA provided guidance on a path forward for addressing the manufacturing issues related to Twirla in its minutes from the End of Review Type A meeting, received by the Company in May 2018.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla® (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15, is an investigational low-dose, non-daily, prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

Follow Agile on LinkedIn and Twitter: @AgileTher.

Xulane® is a registered trademark of Mylan N.V.

Forward-Looking Statements

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions for Twirla. We may, in some cases use terms such as "believes," "potential," "continue," "plans," "may," "might," 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 beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding our intention to meet with the FDA, the timing of which is subject to FDA's discretion and which may not result in a clear agreement on the issues discussed, and our belief that a reformulation of Twirla may not be necessary. 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. These forward looking statements are subject to risks and uncertainties including risks related to the FDA requiring us to reformulate Twirla, our ability to develop a reformulation that will address the FDA's concerns, including showing bioequivalence, if necessary, our ability to successfully complete the suggested wear study and that the results do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, and, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, in addition to the planned correspondence regarding the design of the suggested wear study, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, including a determination by the Advisory Committee that Twirla should not be approved, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory review process for Twirla, our ability to raise capital when needed to complete the development and regulatory review process for Twirla, and unforeseen market factors or events in our clinical and manufacturing development plans and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking

statements. 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, Inc.

Contact:

Investor Relations

Agile Therapeutics

609-683-1880

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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

Thomas D. Kimble[a], Alfred Poindexter[b], Kurt Barnhart[c], Paula M. Castaño[d], Beatrice A. Chen[e], Joseph A. Chiodo III[f], Elizabeth I.O. Garner[f]

[a]Eastern Virginia Medical School, 601 Colley Ave, Norfolk, VA; [b]Advances in Health, Inc., 7515 South Main St Suite 360, Houston, TX; [c]University of Pennsylvania Medical Center, 3701 Market St Suite 810, Philadelphia, PA; [d] Columbia University Irving Medical Center, New York, NY; [e]University of Pittsburgh/Magee-Womens Research Institute, 300 Halket St, Pittsburgh, PA; [f]Agile Therapeutics, 101 Poor Farm Rd, Princeton, NJ.

Agile THERAPEUTICS

Disclosures – Thomas D. Kimble, MD

- Speaker Bureau: Merck, AbbVie, Allergan
- Research Support: Agile, Allergan, Antiva, Bayer, Chemo, Gynesonics, Inovio, Medicines360, Mithra, Sebela
- This study was sponsored by Agile Therapeutics, Inc.

Background

- Yamazaki M, et al. Contraception 2015
  - Meta-analysis concludes that obese women may have a higher pregnancy rate during combination oral contraceptive use compared to non-obese women

Objective

- To perform statistical modeling to identify variables predictive of pregnancy in a prospective Phase III study of an investigational low-dose, weekly transdermal contraceptive containing levonorgestrel and ethinyl estradiol (AG200-15)

AG200-15 Overview

- Investigational transdermal contraceptive delivery system (TCDS)
  - Low dose, Non-daily combination hormonal contraceptive patch
- Daily exposure (24-hour AUC) of levonorgestrel (LNG) and ethinyl estradiol (EE) similar to oral doses of 120 µg LNG and 30 µg EE
- 28-day cycle:
  - 3 weeks of 7-day patches
  - 1 patch-free week

AUC = area under the curve

SECURE Study Design Elements

- A Phase 3 Study to Evaluate Contraception Use, Reliability, and Effectiveness (SECURE)
  - ClinicalTrials.gov NCT02158572
- Single-arm, open-label, 1-year (13-cycle), healthcare-company funded, Phase 3, IRB-approved study
  - Conducted at 102 US sites
  - 2032 women were enrolled
  - Subjects were 18 years of age or older, sexually active, and with regular menses every 21-38 days
  - No eligibility restrictions for weight or body mass index (BMI)

Methods for Statistical Modeling

- **STEP 1** - A series of univariate logistic regression analyses were performed to identify variables predictive of contraceptive failure (i.e., pregnancy)
- **STEP 2** - These variables were used to inform two stepwise regression analyses (SRA1 and SRA2)

- Note – All analyses were performed for women ≤35 years of age

STEP 1 - Variables Used In The Univariate Regression Analysis

- Age (years)
- Race (White, Black or African American, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- Weight (kg)
- Weight Decile
- Weight Median Split
- Weight Quartiles
- BMI (kg/m^2)
- BMI <25, 25 to <30, ≥30
- BMI <30, ≥30
- BMI Median Split
- Smoking Status (Current Smoker, Past Smoker, Non-smoker)
- Alcohol Use in Past 12 Months (Yes, No)
- Education Level (No College Degree, College Degree)
- Naïve to Transdermal Contraception (Yes, No)
- Prior Use of Hormonal Contraceptives (Current, Recent, Former, Naïve)
- Number of Prior Pregnancies
- Prior Pregnancies Category (0, 1, 2, ≥3)
- Late or Missed Patch Application (Yes, No)
- Unscheduled Patch Removal (Yes, No)
- At Least One Reported Patch Partially Detached (>25%) or Completely Detached (Yes, No)
- At Least One Reported Complete Detachment of the Patch (Yes, No)
- Non-compliant, defined as response of No to wearing a patch for 2 or more consecutive days (Yes, No)

Variables that were Positively Related to Contraceptive Failure ($p \leq 0.050$)

- Weight (kg)
- Weight Deciles
- Weight Quartiles
- BMI
- BMI <25, 25 to <30, ≥30
- BMI <30, ≥30
- Number of Prior Pregnancies
- Prior Pregnancies Category (0, 1, 2, ≥3)

Variables that were Negatively Related to Contraceptive Failure ($p \leq 0.050$)

- Unscheduled Patch Removal (Yes, No)
- At Least One Reported Complete Detachment of the Patch

STEP 2 - Stepwise Regression

- Weight and BMI variables were highly correlated in univariate analysis therefore:
- We performed two stepwise regression analyses
  - SRA1 - BMI ≥30 kg/m^2 and <30 kg/m^2
  - SRA2 - Weight deciles

Variables used in Stepwise regression

- Age (years)
- Race (White, Black or African American, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- Smoking Status (Current Smoker, Past Smoker, Non-smoker)
- Alcohol Use in Past 12 Months (Yes, No)
- Education Level (No College Degree, College Degree)
- Prior Use of Hormonal Contraceptives (Current, Recent, Former, Naïve)
- Number of Prior Pregnancies
- Late or Missed Patch Application (Yes, No)
- Unscheduled Patch Removal (Yes, No)
- At Least One Reported Patch Partially Detached (>25%) or Completely Detached (Yes, No)
- At Least One Reported Complete Detachment of the Patch (Yes, No)
- Non-compliant, defined as response of No to wearing a patch for 2 or more consecutive days (Yes, No)
- Obesity and weight

Stepwise Regression Findings

- SRA1 – BMI
  - Number of prior pregnancies: **OR = 1.344** (1.140, 1.583; p < 0.001)
  - BMI ≥30 kg/m2 and <30 kg/m2: **OR = 1.957** (1.186, 3.229; p = 0.009)
  - Patch partially detached*: **OR = 0.441** (0.260, 0.750; p = 0.002)
  - Age: **OR = 0.924** (0.868, 0.983; p = 0.012)
  - Other variables not stat sig (p > 0.050)
- SRA2 - Weight
  - Number of prior pregnancies: **OR = 1.392** (1.175, 1.648; p < 0.001)
  - Weight decile: **OR = 1.145** (1.046, 1.253; p = 0.003)
  - Patch partially detached*: **OR = 0.405** (0.236, 0.693; p < 0.001)
  - Age: **OR = 0.914** (0.858, 0.974; p = 0.005)
  - Other variable not stat sig (p > 0.050)

* At Least One Reported Patch Partially Detached (>25%) or Completely Detached

Conclusion

- These analyses provide strong evidence that weight/BMI are associate with an increased risk of pregnancy in this Phase 3 study
- There were no restrictions on BMI or weight, resulting in a trial with a representative population of women that reflects current trends of the U.S. population
- New clinical trials that are being designed should not restrict weight or BMI, in order to have a study population that is representative of the growing obese population in the US and that will allow for an accurate assessment of contraceptive efficacy

THANK YOU

Exhibit 99.3

Title: 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

Authors: Thomas D. Kimble(a), Alfred Poindexter(b), Kurt Barnhart(c), Paula M. Castaño(d), Beatrice A. Chen(e), Joseph A. Chiodo III(f), Elizabeth I.O. Garner(f)

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Objectives: To evaluate predictors of contraceptive failure (i.e., pregnancy) for an investigational low-dose weekly transdermal contraceptive containing levonorgestrel and ethinyl estradiol (AG200-15).

Methods: The SECURE (Study to Evaluate Contraceptive Use, Reliability and Effectiveness) study was a single-arm, open-label, multicenter Phase 3 trial that enrolled 2032 sexually active females $\geq$18 years old at risk for pregnancy. A new patch is applied weekly for three weeks and no patch is worn during week four. There were no enrollment restrictions on weight or body mass index (BMI). We performed univariate logistic regression analyses to identify variables predictive of contraceptive failure and to inform two stepwise regression analyses (SRA1 and SRA2) for the primary efficacy analysis population (women $\leq$35 years old).

Results: Weight and BMI variables were highly correlated in univariate analysis; we therefore performed SRA1 for BMI $\geq$30 kg/m^2 and <30 kg/m^2 and SRA2 for weight deciles. Variables included were age, race, ethnicity, smoking status, alcohol use, education level, prior use of hormonal contraception, number of prior pregnancies, late/missed patch application, unscheduled patch removal, patch adhesion, compliance, and obesity (SRA1) or weight (SRA2). SRA1 found the odds of contraceptive failure were 1.96 (1.19, 3.23) times greater for obese versus non-obese subjects. SRA2 found for every increase of one decile in weight, the odds of contraceptive failure were multiplied by 1.15 (1.05, 1.25).

Conclusions: Previous studies have reported that obesity affects the efficacy of combined hormonal contraceptives. Data from the SECURE study supports this hypothesis for a low-dose combination hormonal contraceptive patch.