# 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 5, 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**<br>**Princeton, New Jersey**<br>(Address of principal executive offices) | **08540**<br>(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.**

Agile Therapeutics, Inc. ("Agile") a women's healthcare company, will have a poster presentation of additional results from the Phase 3 SECURE study of AG200-15 (Twirla®), an investigational, once weekly, low-dose hormonal contraceptive patch accepted at the American Society for Reproductive Medicine 2018 Scientific Congress & Expo (ASRM) being held October 6th through October 10th, 2018 in Denver, Colorado. Dr. Paula M. Castaño, MD, MPH, Associate Professor of Obstetrics and Gynecoloy at Columbia University Medical Center, will present the poster titled *The Safety Profile of an Investigational Contraceptive Patch in Women With and Without Hormonal Contraceptive Experience*, which includes safety data on AG200-15.

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.

A copy of Agile's poster 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. Poster Presentation to be available between October 6-10, 2018. |



**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 5, 2018

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

# The Safety Profile of an Investigational Contraceptive Patch in Women With and Without Hormonal Co

Paula M. Castaño[a], James A. Simon[b], Beatrice A. Chen[c], Lisa Flood[d], Michelle Previtera[d], Joseph A. Chiodo III[d], Elizabeth I

[a]Columbia University Irving Medical Center, 622 West 168th Street, New York, NY 10032, USA; [b]George Washington University, Women's Health & Research Consultants®, 1850 M Street, NW #450 Washingto Halket Street, Pittsburgh, PA 15213, USA; [d]Agile Therapeutics, 101 Poor Farm Road, Princeton, NJ 08540, USA.

## INTRODUCTION

- AG200-15 (Twirla®) is a transdermal contraceptive delivery system under investigation as a once-weekly prescription contraceptive patch
- AG200-15 delivers daily exposure of 120 µg of levonorgestrel (LNG) and 30 µg of ethinyl estradiol (EE)
- A 28-day cycle consists of consecutive administration of three 7-day patches followed by 7 days off-treatment
- SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) was a 1-year, single-arm, open-label, multicenter Phase 3 study of the contraceptive efficacy, safety and tolerability of AG200-15 (ClinicalTrials.gov NCT02158572)

## OBJECTIVE

- To evaluate the safety of the AG200-15 patch in women with a range of experience with hormonal contraception.

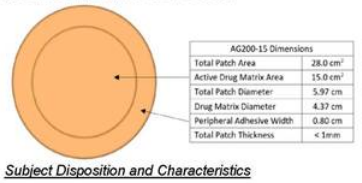
## STUDY DESIGN, MATERIAL, & METHODS

- SECURE employed broad enrollment criteria with no restrictions on body mass index or weight
- Subjects were ≥18 years of age, sexually active, and with menses every 21-38 days
- All study sites were in the U.S.
- Safety was evaluated for women who were:
  - Current (actively using a hormonal contraceptive at study entry) users of hormonal contraception
  - Naive (had never used any hormonal contraceptive) users of hormonal contraception
- Treatment-emergent adverse events (TEAEs) were evaluated and defined as adverse events that occurred from start of treatment to the day after the last patch was removed
- Hormone-related adverse reactions were evaluated and defined as reactions likely caused by combination hormonal contraception

## RESULTS

**Figure 1. Schematic of the AG200-15 Contraceptive Patch**

**(Not an actual patch; Not drawn to scale)**




*Subject Disposition and Characteristics*

- 190 naive users were enrolled in the study and 78 (41%) completed the study (**Table 1**)
- 704 current users were enrolled and 403 (57%) completed the study
- Former and recent users are not presented
- The mean age (in years) of naive users was 24.5 and 27.9 for current users. Further baseline information is presented in **Table 2**

**Table 1: Subject Disposition**

| Disposition Status | Naive Users (%) | Current Users (%) |
|---|---|---|
| Enrolled | 190 | 704 |
| Safety | 190 | 704 |
| Completer | 78 (41) | 403 (57) |
| Reason for Discontinuation | | |
| Any Reason | 112 (59) | 301 (43) |
| Adverse Event | 13 (7) | 93 (13) |
| Death | 0 | 0 |
| Non-Compliance | 22 (12) | 26 (4) |
| Lost to Follow Up | 33 (17) | 48 (7) |
| Subject Decision | 29 (15) | 92 (13) |
| Pregnancy | 7 (4) | 15 (2) |

**Table 2. Baseline Population Characteristics**

| Parameter | Naive Users (n=190) | Current Users (n=704) |
|---|---|---|
| Age, mean (SD) | 24.5 years (5.7) | 27.9 years (6.2) |
| Weight, median (range) | 73.9 kg (39.5-147.0) | 73.8 kg (39.0-144.7) |
| BMI, median (range) | 27.5 kg/m² (16.7-50.7) | 27.4 kg/m² (15.1-51.5) |
| BMI ≥ 30 kg/m²(obese), % | 33 | 29 |
| Black/ African American, % | 31 | 16 |
| White, % | 56 | 75 |
| Hispanic/ Latino, % | 28 | 18 |

- Of current users, 551 (78%) had never used transdermal contraceptives
- The most widely used current hormonal contraceptive method was oral contraceptive pills (33%) (**Table 3**)
- The most used method overall was the male condom with or without spermicide (57%)

**Table 3. Summary of Current Contraceptive Methods**

| Current Contraceptive Method | Users n (%) |
|---|---|
| Oral* | 604 (33) |
| Patch* | 41 (2) |
| Vaginal Ring | 61 (3) |
| Injectable | 1 (0.1) |
| Male Condom with or without Spermicide | 1050 (57) |
| Female Condom with or without Spermicide | 12 (0.7) |
| Diaphragm, Cervical Cap, or Sponge with or without Spermicide | 6 (0.3) |
| Rhythm Method (Fertility Awareness), Withdrawal, or Outercourse | 314 (17) |
| Emergency Contraception | 1 (0.1) |
| Other | 4 (0.2) |

*Two subjects reported both patch and oral

*Safety*

- 2031 participants applied at least one patch and were included in the safety analysis
  - 49% of subjects completed the study
- 1085 (53%) subjects experienced a TEAE (**Table 4**)
- 552 (27%) were definitely related, probably related, or possibly related to study drug
- 224 (11%) subjects discontinued due to an adverse event

**Table 4. Safety Evaluation**

| Category | AG200-15 (%, N=2031) |
|---|---|
| Subjects with Any TEAEs | 1085 (53) |
| Subjects with Any Study Drug-Related* TEAEs | 552 (27) |
| Subjects with Severe TEAEs | 92 (5) |
| Subjects with Serious TEAEs (SAE) | 40 (2) |
| Subjects with Study Drug-Related* Serious TEAEs (SAE) | 15 (0.7) |
| Subjects with TEAEs Resulting in Study Drug Discontinuation | 224 (11) |
| Subjects with TEAEs Resulting in Death | 0 |

*Drug-related: definitely related, probably related, or possibly related.

- For naive users (**Table 5**):
  - 81 (43%) reported TEAEs
  - 16 (8%) reported TEAEs resulting in study drug discontinuation
  - 3 (2%) reported SAEs
  - 2 (1%) reported SAEs resulting in study drug discontinuation
- For current users:
  - 431 (61%) reported TEAEs
  - 92 (13%) reported TEAEs resulting in study drug discontinuation
  - 6 (0.9%) reported SAEs
  - 3 (0.4%) reported SAEs resulting in study drug discontinuation

**Table 5. Summary of TEAEs**

| Parameter | Naive Users (%, n=190) | Current Users (%, n=704) |
|---|---|---|
| TEAEs | 81 (43) | 431 (61) |
| Study-Related* TEAEs | 45 (24) | 221 (31) |
| Severe TEAEs | 6 (3) | 31 (4) |
| Serious TEAEs (SAE) (including death) | 3 (2) | 6 (0.9) |
| Drug-Related* Serious TEAEs (SAE) | 1 (0.5) | 3 (0.4) |
| TEAEs Resulting in Study Drug Discontinuation | 16 (8) | 92 (13) |
| TEAEs Resulting in Death | 0 | 0 |

*Drug-related: definitely related, probably related, or possibly related.

- Hormone-related adverse events reported by at least 2% of naive users were headache (n=8, 4.2%), nausea (n=6, 3.2%), dysmenorrhea (n=5, 2.6%), mood swings (n=4, 2.1%), and acne (n=3, 1.6%)
- For current users, hormone-related adverse reactions reported by at least 2% were nausea (n=27, 3.8%), headache (n= 23, 3.3%), dysmenorrhea (n=21, 3.0%), acne (n=16, 2.3%), and mood swings (n=8, 1.1%)
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**Table 6. Se**

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## DISCLOS

**PC**: Consulta
**JS:** Consulta Radius, Rege Therapeutics AbbVie, Agile Therapeutics
**BC:** Researc Institute. Adv
**LF:** Former e
**MP:** Former
**JC/EG:** Emp

Presented at American Society for Reproductive Medicine 2018 Scientific Congress & Expo October 6-10,