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

May 4, 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.

Agile Therapeutics, Inc. ("Agile") a women's healthcare company, has had 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 Women's Health 2018: Translating Research into Clinical Practice being held May 4th through May 6th, 2018 in Arlington, Virginia. On Friday, May 4, 2018 James Simon, MD, Clinical Professor at George Washington University will present the poster titled *Wearability of a Once-Weekly Low-Dose Contraceptive Pathc in the Phase 3 SECURE Study*, which includes data on the adhesion profile and wearability of 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 dated May 4-6, 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: May 4, 2018

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

Wearability of a Once-Weekly Low-Dose Contraceptive Patch in the Phase 3 SECURE Study

James A. Simon[a], Paula M. Castaño[b], Beatrice A. Chen[c], Elizabeth I.O. Garner[d]

[a]George Washington University, Women's Health & Research Consultants®, 1850 M Street, NW #450 Washington, DC 20036, USA; [b]Columbia University Irving Medical Center, 622 West 168th Street, New York, NY 10032, USA; [c]University of Pittsburgh/Magee-Womens Research Institute, 300 Halket St, 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 (TCDS) under investigation as a once-weekly prescription contraceptive patch (**Figure 1**)
- AG200-15 delivers daily exposure of levonorgestrel (LNG) and ethinyl estradiol (EE) similar to oral doses of 120 µg LNG and 30 µg 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)

OBJECTIVES

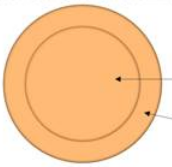
- To examine wearability of the AG200-15 patch and the impact of adhesion and itching/irritation with using the patch.

STUDY DESIGN, MATERIAL, & METHODS

- Women 18 years or older from the US participated
- SECURE employed broad enrollment criteria with no restrictions based on body mass index or weight
- Cycle 1 was excluded from analysis since investigator-reported data for cycle 1 occurred on the day of first patch placement (day of enrollment)
- Patch-related irritation/itching and patch adhesion were evaluated by the investigator at each study visit and daily by the participants through an electronic diary
- Itching scores were graded by participants using a 4-point scale: 0 (none), 1 (mild), 2 (moderate), and 3 (severe)
- Irritation scores were graded by participants and investigators using a 4-point scale: 0 (none), 1 (mild), 2 (moderate), and 3 (severe); for investigators, guidance was given as follows:
  - None: No irritation or barely perceptible/spotty erythema
  - Mild: Mild erythema covering most of the application site or the skin immediately surrounding the application site
  - Moderate: Moderate erythema covering most of the application site or the skin immediately surrounding the application site, with or without presence of mild edema
  - Severe (Significant): Severe erythema of the application site or the skin immediately surrounding the application site, with or without edema, vesiculation, bullae and/or ulceration
- Patch adhesion scores were rated by participants and investigators using a 5-point scale from 0 to 4, with language modified as appropriate for participant or investigator users (**Figure 2**)
  - Adhesion scores of 0 and 1 are combined since 90% of the drug delivering portion of the patch remains attached with these scores.

RESULTS

Figure 1. Schematic of the AG200-15 Contraceptive Patch (Not an actual patch; Not drawn to scale)

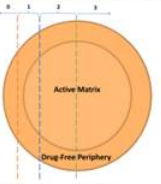


AG200-15 Dimensions	
Total Patch Area	28.0 cm^2
Active Drug Matrix Area	15.0 cm^2
Total Patch Diameter	5.97 cm
Drug Matrix Diameter	4.37 cm
Peripheral Adhesive Width	0.80 cm
Total Patch Thickness	< 1mm

Adhesion

- 2031 participants applied at least one patch and were included in the safety analysis
- Over 13 cycles, investigators reported a worst adhesion score of 0 or 1 at 99.4% of visits.
  - 99.4% and 99.3% investigators reported a worst adhesion score of 0 or 1 for cycle 2 and cycle 13 visits, respectively
- Over 13 cycles, 88.7% of patches were reported by participants to have a worst adhesion score of 0 or 1 (**Table 1**)
  - 84.1% and 92.5% of patches in cycles 2 and 13, respectively, were reported by the participant to have a worst score of 0 or 1
  - 5.0% of the cumulative number of patches applied during the trial were reported by the participant to be completely detached
- 1.5% of participants discontinued from the study due to patch detachments

Figure 2. Five-Point Adhesion Assessment Scale (Not an actual patch; Not drawn to scale)



Score	Investigators	Modified Scale Language for Subjects*
0	>90% adhered (none to minimal lift)	No lifting or small amount of lifting at the edges of the patch
1	≥ 75% adhered but < 90% (some edges showing lift)	More than a small amount of lifting at the edges up to one-quarter of the patch lifting off
2	≥ 50% adhered but < 75% (at least half of system lifts off)	More than one quarter of the patch lifting off up to half of the patch lifting off
3	< 50% (more than half of the patch lifts off, but the patch remains attached)	More than half of the patch is lifting off, but the patch is still on
4	Patch completely detached	Patch has completely come off

Table 1. Percent of Patches by Worst Adhesion Score Reported in a Cycle and Overall (Overall = Reported by Participant At Least Once During the Trial)

Cycle	0 or 1	2, 3, or 4	4
2	84.1	15.9	8.0
3	87.7	12.3	5.8
4	88.9	11.1	4.7
5	89.1	10.9	4.5
6	90.2	9.8	3.9
7	90.9	9.1	3.5
8	92.0	8.0	3.5
9	91.9	8.1	2.8
10	90.9	9.1	3.6
11	92.0	8.0	3.1
12	91.9	8.1	3.1
13	92.5	7.5	2.4
Overall	88.7	11.3	5.0

Irritation/Itching

- For 13 cycles overall, investigators reported a worst skin irritation score of 0 for 95.8% of each visit
  - 96.2% and 94.6% of patches in cycles 2 and 13, respectively, were reported by the investigator to have a worst skin irritation score of 0
- For 13 cycles overall, 82.4% of patches were reported by participants to have a worst skin irritation score of 0 (**Table 2**)
  - 79.7% and 86.5% of patches in cycle 2 and 13, respectively, were reported by the participant to have a worst skin irritation score of 0
- Over 13 cycles, 64.6% of patches were reported by participants to have a worst skin itching score of 0 (**Table 3**)
  - 58.0% and 72.7% of patches in cycle 2 and 13, respectively, were reported by the participants to have a worst itching score of 0
- 1.1% and 0.8% of participants discontinued from the study due to application site irritation and itching respectively

Table 2: Percent of Patches by Worst Irritation Score Reported in a Cycle and Overall (Overall = Reported by Participant At Least Once During the Trial)

Cycle	0	1	2	3
2	79.7	13.4	5.3	1.6
3	81.2	11.7	5.3	1.7
4	80.7	12.4	5.2	1.7
5	83.6	9.9	4.9	1.6
6	83.2	10.2	5.1	1.4
7	83.9	10.3	4.5	1.3
8	83.6	10.3	4.3	1.8
9	84.8	9.6	4.4	1.2
10	84.2	9.2	5.1	1.5
11	84.2	9.8	4.4	1.6
12	85.5	8.5	4.5	1.5
13	86.5	8.8	3.7	1.0
Overall	82.4	11.2	4.9	1.5

0: no skin irritation; 1: mild; 2: moderate; 3: severe.

Table 3: Percent of Patches by Worst Itching Score Repo Overall (Overall = Reported by Participant At Least Once

Cycle	0	1	2
2	58.0	28.8	10.8
3	62.2	25.0	10.4
4	64.4	23.8	9.2
5	66.8	21.4	9.5
6	67.5	21.1	9.1
7	67.6	20.4	9.6
8	66.9	20.9	9.7
9	69.5	19.0	8.9
10	68.4	19.3	9.8
11	70.1	18.3	9.5
12	71.6	17.5	8.6
13	72.7	17.7	8.1
Overall	64.6	23.3	9.8

0: no skin itching; 1: mild; 2: moderate; 3: severe.

CONCLUSIONS

- Participants and investigators reported adhesion scores in sup adhesion
  - Investigators reported good adhesion scores overa adhesion from cycles 2 to 13.
  - Participants reported good adhesion scores and a detachments
- Low patch-related itching and irritation scores were reported b participants indicating favorable wearability
- Participant experience plays a role in patch wearability
  - The percent of patches with adhesion, itching, and increased over the duration of the study,
  - A learning curve for patch application experience a knowledge of patch scoring increased wearability p study
- Low discontinuation rates due to itching/irritation or adhesion adverse events were not bothersome enough to cause par study

DISCLOSURES

JS: Consultant/Advisor: AbbVie, Allergan, AMAG, Amgen, Ascend Radius, Regeneron, Roivant, Sanofi, Sebela, Sermonix, Shionogi, TherapeuticsMD, Valeant; Speaker: Novo Nordisk, Shionogi, Valea AbbVie, Agile, Allergan, Bayer, New England Research Institute, P TherapeuticsMD; Stock Ownership, Sermonix.

PC: Consultant/Advisor: Bayer, Merck; Research Support: Bayer, M

BC: Research support: Medicines 360 and Merck, managed by Ma Institute. Advisory board: Merck.

EG: Employee/Stock Ownership: Agile Therapeutics.

Presented at Women's Health 2018: Translating Research into Clinical Practice, May 4-6, 2018, in Arlington, VA