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

April 27, 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 the 2018 Annual Clinical and Scientific Meeting of the American Congress of Obstetricans and Gynecologists (ACOG) being held April 27th through April 30th, 2018 in Austin, Texas. Dr. Anita Nelson, MD, Professor and Chair, Obstetrics and Gyencology at the College of Osteopathic Medicine of the Pacific, will present the poster titled *The Patch Wear Profile from SECURE: A Once-Weekly Low Dose Contraceptive Patch 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 April 27-30, 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: April 27, 2018

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

The Patch Wear Profile From SECURE: A Once-Weekly Low-Dose Contraceptive Patch Study

Anita L. Nelson[1]; Andrew M. Kaunitz[2]; Robin Kroll[3]; James A. Simon[4]; Paula M. Castaño[5]; Elizabeth I.O. Garner[6]

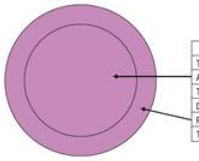
[1]Western University of Health Sciences, Pomona, CA; Professor Emeritus, David Geffen School of Medicine at UCLA, Los Angeles, CA; [2]University of Florida College of Medicine-Jacksonville, Jacksonville, FL; [3]University of Washington, Seattle, WA; [4]George Washington University School of Medicine, Washington, DC; [5]Columbia University Irving Medical Center, New York, NY; [6]Agile Therapeutics, Princeton, NJ.

Introduction

AG200-15 (Twirla®)

- A transdermal contraceptive delivery system (TCDS) under investigation as a once-weekly prescription contraceptive patch (**Figure 1**)
  - A 28-day cycle includes: 3 weeks of 7-day patches and 1 patch-free week

Figure 1. Schematic of AG200-15 TCDS: A Once-Weekly Contraceptive 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	<1 mm

- Delivers daily exposure of levonorgestrel (LNG) and ethinyl estradiol (EE) similar to oral doses of 120 µg of LNG and 30 µg of EE

SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness)

- A 1-year, single-arm, open-label, multicenter phase 3 study of the contraceptive efficacy, safety, and tolerability of AG200-15 TCDS
- Broad enrollment criteria with no limits on body mass index (BMI) or weight
- Yielded a Pearl Index for participants age 18 to 35 years of 4.8 (upper bound of 95% confidence interval, 6.1), with an adverse event (AE) profile similar to approved combined hormonal contraceptives (Nelson et al., ACOG 2017, abstract #22A)

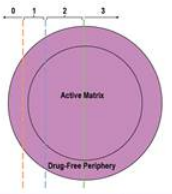
Objective

- Here we examine various aspects of patch adhesion and wearability with the AG200-15 TCDS

Methods

- The SECURE trial was conducted in US women 18 years or older with no restriction on BMI or weight (ClinicalTrials.gov NCT02158572)
- Patch-related irritation/itching and patch adhesion were evaluated by the investigator at each visit and by the participants through an electronic diary
- Irritation scores were graded using a 4-point scale:
  - 0 (None): No irritation or barely perceptible/spotty erythema
  - 1 (Mild): Mild erythema covering most of the application site or the skin immediately surrounding the application site
  - 2 (Moderate): Moderate erythema covering most of the application site or the skin immediately surrounding the application site, with or without presence of mild edema
  - 3 (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
- Itching scores were graded by participants using a 4-point scale: 0 (none), 1 (mild), 2 (moderate), and 3 (severe)
- Patch adhesion scores were rated by participants and investigators using a scale from 0 to 4 (**Figure 2**)

Figure 2. Five-Point Adhesion Assessment Scale (Not drawn to scale)



Score	Investigators	Modified Scale Language for Participants
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

Results

- 2031 participants received at least one patch and were included in the safety analysis
- 93% of patch applications were scheduled, demonstrating that participants rarely required unscheduled patch changes (replacements)
- A decreasing trend in the percent of unscheduled patch changes (replacements) was observed from Cycle 1 to Cycle 13, showing improvement with increasing participant experience

Irritation/Itching

- Across all patches applied in each cycle, 77.6% of participants reported a 0 (none) in Cycle 1 and 86.5% reported a 0 in Cycle 13 for their worst skin irritation
- Overall, across all cycles and all patches applied, 93.6% of participants reported their worst skin irritation score as none or mild; only 1.5% reported their worst skin irritation score as severe (**Table 1**)

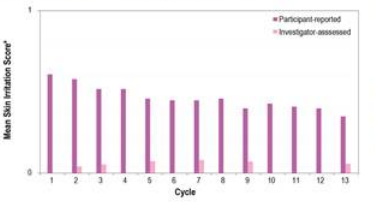
Table 1. Participant-Reported Skin Irritation Score for Each Patch per Cycle and Overall

	Skin Irritation Score* (%)			
Cycle	0	1	2	3
1	77.6	16.1	5.3	1.0
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

*Worst score during a cycle or overall for each patch.
0: no skin irritation; 1: mild; 2: moderate; 3: severe.

- For Cycles 1-13 combined, the participant-reported mean skin irritation score was 1.31
  - Participant-reported mean skin irritation scores by cycle were low and generally decreased over time (**Figure 3**)
- For Cycles 1-13 combined, using the worst irritation score for each participant, the investigator-assessed mean skin irritation score was 0.18
  - Investigator-assessed mean skin irritation scores by cycle were low (**Figure 3**)

Figure 3. Mean Skin Irritation Scores by Cycle, as Reported by Participants and Assessed by Investigators



Investigator assessments did not occur at every cycle.
*Worst score during a cycle for each participant; 0: no skin irritation; 1: mild; 2: moderate; 3: severe.

- Overall, 85.0% and 12.6% of participants were determined by the investigator to have none or mild skin irritation, respectively
- 14.6%, 29.1%, and 37.6% of participants reported their worst itching score as none, mild, or moderate, respectively
- Overall the mean participant-reported skin itching score was 1.6

Adhesion

- **Participant-reported patch adhesion:** Across all patches over the 7-day wear period, the mean patch adhesion score was 0.16 (**Table 2**)
  - When assessed by patch wear day, on average, 89.6% of patches had adhesion of ≥90% (scores of 0)
  - The percent of patches per day that completely detached decreased from 2.1% to 0.7%

Table 2. Participant-Reported Patch Adhesion Over the 7-Day Wear Period

	% of Patches with Relevant Adhesion Score					Mean Daily Adhesion Score
Patch Wear Day	0	1	2	3	4	
1	90.2	5.6	1.3	0.8	2.1	0.19
2	95.7	3.0	0.4	0.2	0.7	0.07
3	93.2	5.3	0.7	0.3	0.5	0.10
4	90.2	7.2	1.2	0.5	0.8	0.15
5	87.4	9.4	1.6	0.7	0.8	0.18
6	84.9	11.1	2.2	1.0	0.8	0.22
7	82.8	12.7	2.6	1.4	0.7	0.24
*Average	89.6	7.4	1.4	0.7	1.0	0.16

*Average is weighted mean to account for no. of measurements for each patch wear day.
0: no lifting or small amount of lifting at edges of the patch; 1: more than a small amount of lifting at the edges up to one-quarter of the patch lifting off; 2: more than one-quarter of the patch lifting off up to half of the patch lifting off; 3: more than half of the patch is lifting off, but the patch is still on; 4: patch detached.

- **Investigator-rated patch adhesion:** Across all patches over the 7-day wear period, the mean patch adhesion score was 0.04 (**Table 3**)
  - When assessed by patch wear day, on average, 96.9% of patches had adhesion of ≥90% (scores of 0)
  - In total, 0.2% of patches were rated as completely detached

Table 3. Investigator-Rated Patch Adhesion Over the 7-Da Wear Period

	% of Patches with Relevant Adhesion Score					Me Ad
Patch Wear Day	0	1	2	3	4	
1	98.0	1.6	0.1	0	0.2	
2	97.4	2.0	0.4	0.1	0.2	
3	96.1	3.6	0.2	0	0.2	
4	94.6	4.6	0.5	0.2	0.2	
5	92.9	6.7	0.2	0	0.2	
6	94.4	5.0	0.6	0	0	
7	95.1	4.5	0.4	0	0	
*All Days	96.9	2.7	0.2	0	0.2	

*Average is weighted mean to account for number of measurements for each patch wear day.
0: ≥90% adhered (none to minimal lift); 1: ≥75% adhered but <90% (some edge showing lift); 2: ≥50 but <75% (at least half of system lifts off); 3: <50% (> half of system lifts off, but patch remains attac patch detached.

Adverse Events/Discontinuations

- Across 13 cycles, 6.2% of participants reported a local site reaction
- Treatment discontinuation due to application site irritation/itching occu 1.9% of participants
- The overall participant discontinuation rate from the study was 51.3%
  - Of participants who reported at least one patch detachment, 46.3% discontinued from the trial vs. 53.7% that completed
  - Of participants who did not report a patch detachment, 61.0% disco from the trial vs. 39.0% that completed

Conclusion/Implications

- Overall, results of participant- and investigator-rated patch characteris indicate favorable patch adhesion and wearability of the AG200-15 TC
- Rates of skin irritation were generally low
- The rate of local site reactions was low and treatment discontinuation application site irritation/itching occurred in <2% of participants
- Adhesion analysis across a 7-day period of patch wear suggests a fav patch adhesion profile
- Patch detachments did not contribute to participants leaving the study participants reporting any detachments during the trial did not disconti the trial at a higher rate than those that did not report any patch detac

Disclosures

AN: Consultant/Advisor: Agile, AMAG Pharma, Bayer, ContraMed, Merck, Pharmanest; Speaker: Allergan, Bayer, Merck; Grants/Research Support: Agile, ContraMed, Estetra S Evofem Inc, FHI (MonaLisa), Mathra Pharma, Merck. **AK:** Consultant/Advisor: Bayer, Me Mithra; Consultant (institution): Medicines360; Research Support (institution): Agile, Allen Bayer, Evofem, Merck, Mithra. **RK:** Research Support: AbbVie, Agile, Allergan, Bayer, Ch Group, Contramed, Merck, Mithra. **JS:** Consultant/Advisor: AbbVie, Allergan, AMAG, Am Ascend, Azure, Millendo, Nuelle, Radius, Regeneron, Roivant, Sanofi, Sebela, Sermonix Symbiotec, TherapeuticsMD, Valeant; Speaker: Novo Nordisk, Shionogi, Valeant; Resea Support: AbbVie, Agile, Allergan, Bayer, New England Research Institute, Palatin, Symbi TherapeuticsMD; Stock Ownership: Sermonix. **PC:** Consultant/Advisor: Bayer; Research Bayer. **EG:** Employee/Stock Ownership: Agile Therapeutics.

Acknowledgements

Funding to support the development this poster was provided by Agile Therapeutics to MedVal Scientific Information Services, LLC, Princeton,

Presented at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting, April 27-30, 2018, Austin, TX