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

June 28, 2019
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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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 June 28, 2019, Agile Therapeutics, Inc. ("Agile") a women's healthcare company, presented a poster on adhesion and safety data from two Phase 1 in vivo wear studies at Women's Health 2019 being held June 28-30, 2019 at Virginia Commonwealth Universtiy in Norfolk, Virginia. The poster, titled "*Results of Two Phase 1 Clinical Trials on the Adhesion Profile of AG200-15, An Investigational Transdermal Contraceptive Delivery System,"* will be available through June 29, 2019. Agile had previously presented the poster in March 2019, but the newly presented poster now presents additional adhesion data in Table 7.

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 available on June 28-29, 2019.

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: June 28, 2019

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

Results of Two Phase 1 Clinical Trials on the Adhesion Profile of AG200-15, An Investigational Transdermal Contraceptive Delivery System

Terrance Ocheltree, PhD[a], Janet Wittes, PhD[b], Jessica Case, MPH[b], Michael Tuley, PhD[c], Irina Krause, MS[c], Elizabeth I.O. Garner, MD, MPH[d], Joseph Chiodo III, PharmD[d]

[a]PharmTree Consultants, LLC, Libertyville, IL, USA; [b]Statistics Collaborative, Inc., Washington, DC, USA; [c]TKL Research Inc., Fair Lawn, NJ, USA; Columbia University Irving Medical Center, 622 West 168th Street, New York, NY 10032, 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**)

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

- AG200-15 delivers 120 µg of levonorgestrel and 30 µg of ethinyl estradiol daily
- A 28-day cycle consists of consecutive administration of three 7-day patches followed by 7 days off-treatment
- We report two Phase 1 in-vivo, single center wear studies: a single-arm study (ATI-CL26) and a crossover study (ATI-CL25) comparing AG200-15 to Xulane®, a marketed generic TCDS hormonal contraceptive containing norelgestromin and ethinyl estradiol (**Figure 2**)

Figure 2. Schematic of the AG200-15 Contraceptive Patch
(Not drawn to scale)

Xulane Dimensions	
Total Patch Area (same as active drug matrix area)	14 cm²
Total Patch Diameter	4 cm
Total Patch Thickness	<1mm

STUDY DESIGN, MATERIAL, & METHODS

- ATI-CL26 was a 7-day, single-arm pilot study of AG200-15
- ATI-CL25 subjects were randomized to wear AG200-15 or Xulane for Week 1; they then switched to the patch not initially worn for Week 2
- Both studies enrolled 18 - 35 year-old women with BMI < 35 kg/m^2 who remained in the clinic for the duration of the studies
- Patch adhesion was assessed daily by trained study site personnel using a five-point scale (**Table 1**)
  - Patch tracers held a transparent diagram over the patch and lifted areas were marked using a permanent marker
  - Patch graders (separate from the tracers) provided grading for the percentage of patch lifting
  - Each tracer and grader were blinded to any previous assessments

Table 1. Adhesion Scale

Score	Adhesion
0	≥ 90% adhered (essentially no lift off the skin)
1	≥ 75% to < 90% adhered (some edges only lifting off the skin)
2	≥ 50% to < 75% adhered (less than one-half of the patch lifting off the skin)
3	> 0% to < 50% adhered (not detached, but greater than one-half of the patch lifting off the skin without falling off)
4	0 % adhered (patch detached; completely off the skin)

- Subjects could conduct activities of daily living and could not re-adhere patches that were partially detached or use overlays, tape or other coverings
- The primary objective of ATI-CL26 was to evaluate the adhesion of AG200-15 over 7 days; descriptive statistics, including mean patch adhesion scores and number and percent of subjects with scores ≥ 90% and ≥ 75% were assessed
- The primary objective of ATI-CL25 was to evaluate the adhesion of AG200-15 patch over 7 days/168 hours compared to the 7-day adhesion of the Xulane TCDS; AG200-15 would be considered statistically non-inferior to Xulane if the upper 95% confidence limit (95% CL) of the mean difference in adhesion scores was below +0.15
- All analyses used the worst score carried forward method, such that the highest adhesion score for a subject using the five-point scale assessed at any time point after baseline is used for the subsequent time points until a higher score is assessed for that subject

Subject Disposition & Demographics

- ATI-CL26 screened 54 subjects, 30 subjects were randomized into the study and received study drug; all subjects completed the study. Demographics are summarized in **Table 2**

Table 2. ATI-CL26 Demographics

Parameter	AG200-15 (N=30)
Age (years), mean (SD)	28.3 (5.2)
Weight (kg), mean (SD)	69.0 (10.1)
Height (cm), mean (SD)	160.8 (4.6)
BMI (kg/m2), mean (SD)	26.7 (3.9)
Race, n (%)	
White	10 (33.3%)
Black or African American	18 (60.0%)
Other	2 (6.7%)
Ethnicity, n (%)	
Hispanic or Latino	13 (43.3%)
Not Hispanic or Latino	17 (56.7%)

- ATI-CL25 screened 135 subjects; 83 subjects were randomized into the study and received study drug; 79 subjects completed the study; 77 subjects were included in the per protocol analysis population (two subjects were excluded from the analysis for a protocol violation). Demographics are summarized in **Table 3**

Table 3. ATI-CL25 Demographics

Parameter	Subjects (N=83)
Age (years), mean (SD)	27.3 (4.8)
Weight (kg), mean (SD)	68.3 (10.8)
Height (cm), mean (SD)	161.4 (5.9)
BMI (kg/m2), mean (SD)	26.2 (3.9)
Race, n (%)	
White	26 (31.3%)
Black or African American	52 (62.7%)
Other	5 (6.0%)
Ethnicity, n (%)	
Hispanic or Latino	22 (26.5%)
Not Hispanic or Latino	61 (73.5%)

RESULTS

ATI-CL26

- For ATI-CL26 the overall mean score for all 30 subjects was 0.08 (SD 0.26) (**Table 4**)
- Overall, 96.7% of subjects had a mean adhesion score < 1 (i.e., ≥ 90% adhesion) and 100% of subjects had a mean adhesion score < 2 (i.e., ≥ 75% adhesion) (**Table 5**)
- There were no complete detachments; 2 subjects had an adhesion score ≥ 2 at any time point, these occurred on Day 6 and Day 7 of the study

Table 4. ATI-CL26 Adhesion Scores

	N	Mean (SD)
Overall	30	0.08 (0.26)

Table 5. ATI-CL26 Adhesion ≥ 90% and ≥ 75%

	AG200-15 (N=30) n (%)
Subjects with mean adhesion score < 1 (≥90% adhesion)	29 (96.7)
Subjects with mean adhesion score < 2 (≥75% adhesion)	30 (100)

ATI-CL25

- For ATI-CL25, the overall mean score for AG200-15 subjects was 0.14 (SD 0.28) and for Xulane was 0.39 (SD 0.40). Results for all time points are presented in (**Table 6**)
- The study met the non-inferiority criterion by demonstrating a mean difference of -0.24 and upper 95% confidence limit of -0.16 (**Table 7** and **Figure 3**)

Table 6. ATI-CL25 Mean Adhesion Scores

	AG200-15 (N = 77)	*Xulane (N = 77)*	*Difference (AG200-15 – Xulane)*		
	Mean (SD)	Mean (SD)	Mean (SD)	One-sided upper 95% CI	Non-inferiority Criteria Met
Per Protocol population	0.14 (0.28)	0.39 (0.40)	- 0.24 (0.46)	- 0.16	YES

[1] One subject is excluded from the primary endpoint mean calculation because her data cannot be analyzed using a paired t-test

Figure 3. Non-inferiority Scale

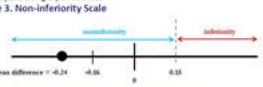

Table 7. ATI-CL25 Adhesion ≥ 90% and ≥ 75%

	AG200-15 (N=78) n (%)
Subjects with mean adhesion score < 1 (≥90% adhesion)	58 (74.4)
Subjects with mean adhesion score < 2 (≥75% adhesion)	77 (98.8)

Safety

ATI-CL26

- Overall, 14/30 (46.7%) of the subjects experienced at least one TEAE (**Table 8**)
- All adverse events were mild except one subject reported an event that was considered moderate in severity (fatigue)
- Two adverse events were considered unrelated to study drug (skin discoloration and acne), the remainder were considered possibly related by the investigator
- There were no TEAEs that led to study-drug discontinuation, no SAEs, and no deaths during the course of the study

Table 8. ATI-CL26 Adverse Events

System Organ Class	AG200-15 (N=30)
Any adverse events	14 (46.7%)
Nervous system disorders	8 (26.7%)
Headache	8 (26.7%)
Gastrointestinal disorders	5 (16.7%)
Vomiting	3 (10.0%)
Abdominal pain	2 (6.7%)
Nausea	1 (3.3%)
Skin and subcutaneous tissue disorders	3 (10.0%)
Acne	1 (3.3%)
Hives	1 (3.3%)
Skin discoloration	1 (3.3%)
Reproductive system and breast disorders	2 (6.7%)
Menstrual cramps	2 (6.7%)
General disorders and administration site conditions	1 (3.3%)
Fatigue	1 (3.3%)

Note: Adverse events are coded using MedDRA and are sorted by decreasing SOC frequency. Subjects are counted once for each system organ class. A TEAE is an adverse event with an onset date on or after the first patch application through Day 8 (day of final study visit).

ATI-CL25

- Overall, 49/83 (59.0%) of the subjects experienced at least one TEAE, 32/81 (39.5%) and 36/81 (44.4%) of subjects for the AG200-15 and Xulane treatment periods, respectively (**Table 9**)
- There were no TEAEs that led to study-drug discontinuation, no SAEs, and no deaths during the course of the study

Table 9. ATI-CL25 Adverse Events (occurring in over 2% of subjects in either treatment period)

System Organ Class	AG200-15 (N=81)	Xulane (N=81)
Any adverse events	32 (39.5%)	36 (44.4%)
Skin and subcutaneous tissue disorders	11 (13.6%)	8 (9.9%)
Eczema	3 (3.7%)	2 (2.5%)
Pruritus	3 (3.7%)	2 (2.5%)
Rash	4 (4.9%)	1 (1.2%)
Reproductive system and breast disorders	8 (9.9%)	8 (9.9%)
Breast tenderness	4 (4.9%)	3 (3.7%)
Metrorrhagia	3 (3.7%)	3 (3.7%)
Respiratory, thoracic and mediastinal disorders	0	5 (6.2%)
Nasal congestion	0	2 (2.5%)
General disorders and administration site conditions	2 (2.5%)	3 (3.7%)
Administration site rash	2 (2.5%)	1 (1.2%)

Note: Adverse events are coded using MedDRA and are sorted by decreasing SOC frequency. Subjects are counted once for each system organ class. Adverse events are analyzed based on the treatment last applied prior to the onset of the AE.

CONCLUSIONS

- Overall, the ATI-CL26 and ATI-CL25 studies support an acceptable in-vivo adhesion profile of AG200-15
- In ATI-CL25, AG200-15 demonstrated non-inferiority compared to Xulane since the upper 95% CL was -0.16 which was below the prespecified +0.15 non-inferiority criterion.
- Both TCDS were generally well-tolerated

Presented at VCU Women's Health 2019, June 28-30, 2019, in Norfolk, VA