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

September 7, 2017
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**	**08540**
(Address of principal executive offices)	(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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ 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 September 7, 2017, Agile Therapeutics, Inc. ("Agile") a women's healthcare company, announced that an abstract presenting data from the Phase 3 SECURE study of its investigational low-dose combined hormonal contraceptive patch (AG200-15) has been selected for an oral presentation during the American Society for Reproductive Medicine (ASRM) Annual Congress being held October 28th through November 1st, 2017 in San Antonio, Texas. The abstract, titled "*Selected Efficacy And Bleeding/Spotting Outcomes From The SECURE Trial: A Phase 3 Study Of AG200-15, An Investigational Weekly Transdermal Contraceptive Patch,"* will be available in the September 2017 issue of *Fertility and Sterility* and online at www.fertstert.org.

Copies of Agile's press release and abstract are attached hereto as Exhibit 99.1 and 99.2, 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 September 7, 2017.
99.2	Agile Therapeutics, Inc. Abstract dated September 7, 2017.

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: September 12, 2017

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

Exhibit 99.1

Agile Therapeutics to Present Additional Phase 3 Data at the 73rd Annual Congress of the American Society for Reproductive Medicine

PRINCETON, NJ, September 07, 2017 - Agile Therapeutics, Inc., (NASDAQ:AGRX), a women's healthcare company, today announced that an abstract presenting data from the Phase 3 SECURE study of its investigational low-dose combined hormonal contraceptive patch (AG200-15) has been selected for an oral presentation during the American Society for Reproductive Medicine (ASRM) Annual Congress being held October 28th — November 1st, 2017 in San Antonio, TX. The abstract, titled "*Selected Efficacy And Bleeding/Spotting Outcomes From The SECURE Trial: A Phase 3 Study Of AG200-15, An Investigational Weekly Transdermal Contraceptive Patch,"* will be available in the September 2017 issue of *Fertility and Sterility* and online at www.fertstert.org.

The SECURE study evaluated the safety and efficacy of the investigational transdermal contraceptive patch AG200-15, known as Twirla®, in a diverse, real-world population of women reflective of current weight trends in the United States. The presentation will include efficacy and safety findings for the overall population and pre-specified body mass index (BMI) categories, in addition to results on the bleeding profile not previously reported.

About Agile Therapeutics

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®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adhesion and patient wearability. For more information, please visit the company website at www.agiletherapeutics.com. Follow Agile on social media: @agilether. The company may occasionally disseminate material, nonpublic information on the company website.

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Source: Agile Therapeutics

Contact: Mary Coleman
Agile Therapeutics, Inc.
609-356-1921

SELECTED EFFICACY AND BLEEDING/SPOTTING OUTCOMES FROM THE SECURE TRIAL: A PHASE 3 STUDY OF AG200-15, AN INVESTIGATIONAL WEEKLY TRANSDERMAL CONTRACEPTIVE PATCH

Anita L. Nelson,(1) Andrew M. Kaunitz,(2) Robin Kroll,(3) James A. Simon,(4) Alfred N. Poindexter,(5) Joseph A. Chiodo,(6) Lisa Flood,(6) Elizabeth I.O. Garner(6)

(1)Los Angeles Biomedical Research Institute, Los Angeles, CA, USA; (2)University of Florida College of Medicine-Jacksonville, Jacksonville, FL, USA; (3)Seattle Women's, Seattle, WA, USA; (4)George Washington University School of Medicine, Washington, DC, USA; (5)Baylor College of Medicine, Houston, TX, USA; (6)Agile Therapeutics, Princeton, NJ, USA

Objective: To assess selected efficacy and bleeding/spotting outcomes with the use of AG200-15 (levonorgestrel and ethinyl estradiol patch).

Design: The SECURE trial was a single-arm, open-label, 1-year (13-cycle), healthcare-company funded, Phase 3, IRB-approved study conducted at 102 US sites (Clinical Trials Identifier: NCT02158572). SECURE had no eligibility restrictions for weight or body mass index (BMI).

Materials and Methods: Pre-specified efficacy analyses in various subgroups were assessed using the Pearl Index (PI). Study subjects receiving AG200-15 recorded vaginal bleeding (requiring use of at least one tampon or sanitary pad) and spotting (requiring use of pantyliners only or no sanitary protection) daily in electronic diaries.

Results: A total of 2,031 subjects wore at least one patch and were included in the safety population (median age 26.0 years [range, 18, 60]; median BMI 26.8 kg/m^2; median weight 71.9 kg); 1,736 subjects age ≤35 years were included in the efficacy analysis. A total of 2,017 subjects provided information on scheduled and unscheduled bleeding/spotting episodes by cycle (Table 1). The PI for women ≤35 years of age was 4.80 (95% CI, 3.55, 6.06). When analyzed by BMI, the PI was 4.22 and 5.41 in women with a BMI <26.8 kg/m^2 and ≥26.8 kg/m^2, respectively. Similarly, when analyzed by weight, the PI was 3.83 and 5.84 in women with a weight <71.9 kg and ≥71.9 kg, respectively. When analyzed by race, the PIs for subjects identifying as white, black/African American, and "other" were 5.06, 4.52 and 3.64, respectively; whereas when analyzed by ethnicity, the PIs for subjects identifying as Hispanic/Latino and non-Hispanic/Latino were 3.65 and 5.07, respectively. The most common hormone-related treatment-emergent adverse events were nausea (4.1%), headache (3.6%) and mood swings/changes/depression (2.8%).

Table 1. Mean Number of Bleeding/Spotting Episodes and Days Per Episode (±SD) By Cycle

	Cycle 2		Cycle 8		Cycle 13	
	No. of episodes	Days per episode	No. of episodes	Days per episode	No. of episodes	Days per episode
Scheduled bleeding and/or spotting	0.6±0.56	4.70±1.90	0.7±0.58	4.50±2.03	0.6±0.60	4.05±2.06
Scheduled bleeding-only	0.6±0.54	3.71±1.57	0.7±0.54	3.55±1.58	0.7±0.56	3.22±1.57
Scheduled spotting-only	0.6±0.71	1.62±1.07	0.6±0.69	1.52±0.99	0.6±0.74	1.41±0.77
Unscheduled bleeding and/or spotting	0.6±0.67	6.25±4.02	0.5±0.65	5.50±3.84	0.5±0.64	5.15±3.31
Unscheduled bleeding-only	0.4±0.58	4.66±2.96	0.4±0.56	3.96±2.52	0.4±0.54	3.74±2.25
Unscheduled spotting-only	0.5±0.71	2.20±1.72	0.4±0.65	2.18±1.81	0.4±0.64	2.09±1.73

An episode of bleeding and/or spotting was defined as one or more consecutive days of bleeding/spotting bounded on either end by ≥2 days of no bleeding or spotting. Unscheduled bleeding/spotting was defined as bleeding/spotting on days when not wearing a patch.

Conclusions: The efficacy of AG200-15, as assessed by the PI, differed by subgroups based on BMI, weight, and race/ethnicity. The mean number of bleeding/spotting episodes were generally similar throughout the study, while the length of episodes generally decreased.

Annotations

Results: A total of 2,031 subjects wore at least one patch and were included in the safety population (median age 26.0 years [18, 60]; median BMI 26.8 kg/m^2; median weight 71.9 kg) and 1,736 subjects age ≤35 years were included in the efficacy analysis. **[Table 14.1.1.1 run date 28Feb17; Table 14.1.2 run date 16Feb17]** A total of 2,017 subjects provided information on scheduled and unscheduled bleeding/spotting episodes per cycle (Table 1). **[Table 14.2.7.1.1 run date 23Mar17]** The PI for women ≤35 years of age was 4.80 (95% confidence interval: 3.55, 6.06). **[Table 14.2.1.2.1 run date 16Feb17; Figure 1 run date 31Mar17]** When analyzed by BMI, the PI was 4.22 and 5.41 in women with a BMI <26.8 kg/m^2 and >26.8 kg/m^2, respectively. **[Figure 2, run date 31Mar17]** Similarly, when analyzed by weight, the PI was 3.83 and 5.84 in women with a weight <71.9 kg and >71.9 kg, respectively. **[Figure 3, run date 31Mar17]** When analyzed by race, the PIs for subjects identifying as white, black/African American, and "other" were 5.06, 4.52 and 3.64, respectively; whereas when analyzed by ethnicity, the PIs for subjects identifying as Hispanic/Latino and non-Hispanic/Latino were 3.65 and 5.07, respectively. **[Figure 4, run date 31Mar17]** The most common hormone-related treatment-emergent adverse events were nausea (4.1%), headache (3.6%) and mood swings/changes/depression (2.8%). **[51882 ACOG poster]**

Table 1. Mean Number of Bleeding/Spotting Episodes (±SD) and Mean Number of Days Per Episode By Cycle **[Table 14.2.7.1.1 run date 23Mar17]|[Table 14.2.7.2.1 run date 23Mar17]|[Table 14.2.7.3.1 run date 23Mar17]|[Table 14.2.7.4.1 run date 23Mar17]|[Table 14.2.7.5.1 run date 23Mar17]|[Table 14.2.7.6.1 run date 23Mar17]**

	Cycle 2		Cycle 8		Cycle 13	
	No. of Episodes	Days per episode	No. of Episodes	Days per episode	No. of Episodes	Days per episode

Scheduled bleeding and/or spotting	0.6±0.56	4.70±1.90	0.7±0.58	4.50±2.03	0.6±0.60	4.05±2.06
Scheduled bleeding-only	0.6±0.54	3.71±1.57	0.7±0.54	3.55±1.58	0.7±0.56	3.22±1.57
Scheduled spotting-only	0.6±0.71	1.62±1.07	0.6±0.69	1.52±0.99	0.6±0.74	1.41±0.77
Unscheduled bleeding and/or spotting	0.6±0.67	6.25±4.02	0.5±0.65	5.50±3.84	0.5±0.64	5.15±3.31
Unscheduled bleeding-only	0.4±0.58	4.66±2.96	0.4±0.56	3.96±2.52	0.4±0.54	3.74±2.25
Unscheduled spotting-only	0.5±0.71	2.20±1.72	0.4±0.65	2.18±1.81	0.4±0.64	2.09±1.73

An episode of bleeding and/or spotting was defined as one or more consecutive days of bleeding/spotting bounded on either end by $\geq$ 2 days of no bleeding or spotting. **[CSR draft1 24Mar17/p44]**