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, 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**	**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)

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

Title of each class	**Trading Symbol**	**Name of exchange on which registered:**
Common stock, par value $0.0001 per share	AGRX	The Nasdaq Capital Market

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

On May 4, 2019, the Company presented an ePoster of combined safety data from the three Phase 3 studies of Twirla® (AG200-15), an investigational, once weekly, low-dose hormonal contraceptive patch, at the 2019 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG) that was held from May 3rd through May 6th, 2019 in Nashville Tennessee. Lead author Dr. Anita Nelson, MD, Professor and Chair of Obstetrics and Gynecology, Western University of Health Sciences presented the poster titled, "*Safety of AG200-15, an Investigational Transdermal Patch, in Three Phase 3 Studies*."

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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: May 6, 2019

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

Safety of AG200-15, an Investigational Transdermal Patch, in Three Phase 3 Studies

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

[1] Western University of Health Sciences, Pomona, CA, David Geffen School of Medicine, 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, and IntimMedicine Specialists, Washington, DC; [5] Columbia University Irving Medical Center, New York, NY [6] Agile Therapeutics, Princeton, NJ

INTRODUCTION

- AG200-15 (Twirla®) is a low-dose transdermal contraceptive delivery system under investigation as a once-weekly prescription contraceptive patch (**Figure 1**)
- A 28-day cycle consists of consecutive administration of three 7-day patches followed by 7 days without treatment
- We report the safety from three Phase 3 studies - the SECURE (ATI-CL23) study, ATI-CL12, and ATI-CL13

Figure 1. Schematic of the AG200-15 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	< 1mm

AIM

- To present the safety and tolerability profile of the investigational combined hormonal contraceptive patch, AG200-15, in women of child bearing potential

STUDY DESIGN, MATERIAL, & METHODS

- SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) was a single-arm, 13-cycle, open-label study conducted in 2014-2016
- ATI-CL12 (13-cycles) and ATI-CL13 (6-cycles) were open-label, randomized, active-controlled (approved oral contraceptives (OC)) safety and efficacy studies conducted in 2010-2011
- All study sites were in the U.S.
- 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 by the investigators and defined as reactions likely caused by combination hormonal contraception

Agile® THERAPEUTICS

RESULTS

- Across all three Phase 3 studies 6,556 subjects were screened and 3,611 were enrolled; ATI-CL23 accounted for over half of these subjects (**Table 1**)
- Overall the mean age was 27.0, mean BMI was 27.9 (15.1 kg/m^2 to 63.0 kg/m^2), 35.1% were obese (BMI ≥30 kg/m^2), 69.4% were White, 23% were Black or African American, and 18.3% were Hispanic or Latino
- The safety population includes subjects who wore at least one patch for any length of time. Approximately half of the subjects who wore at least one patch completed the studies
- The most common reasons for discontinuation of study drug were subject decision, lost to follow-up and adverse events
- The percentage of subjects lost to follow-up was lower in ATI-CL23 than in previous Phase 3 studies (ATI-CL12/13) combined

Table 1. Phase 3 Studies Subject Disposition

	ATI-CL12/13		ATI-CL23	Overall
Cycles	1-6 (CL13)	1-13 (CL12)	1-13	All
Women Screened	2243	2523	4033	6556
Randomized/Enrolled	1330	1579	2032	3611
Safety Population	1220	1450	2031	3481
Completed Study	597 (48.9%)	747 (51.5%)	989 (48.7%)	1736 (49.9%)
Reason for Discontinuation				
Any	623 (51.1%)	703 (48.5%)	1042 (51.3%)	1745 (50.1%)
Subject Decision	176 (14.4%)	200 (13.8%)	310 (15.3%)	510 (14.7%)
Lost to Follow-up	207 (17.0%)	229 (15.8%)	229 (11.3%)	458 (13.2%)
Adverse Events	135 (11.1%)	151 (10.4%)	222 (10.9%)	373 (10.7%)
Non-compliance	42 (3.4%)	47 (3.2%)	116 (5.7%)	163 (4.7%)
Pregnancy	38 (3.1%)	46 (3.2%)	73 (3.6%)	119 (3.4%)
Investigator's Decision	14 (1.1%)	16 (1.1%)	17 (0.8%)	33 (0.9%)
Protocol Violation	4 (0.3%)	4 (0.3%)	14 (0.7%)	18 (0.5%)
Sponsor Decision	0	0	18 (0.9%)	18 (0.5%)
Sponsor Decision (Study Termination)	0	0	2 (0.1%)	2 (0.1%)
Death	0	0	0	0
Other	8 (0.7%)	10 (0.7%)	41 (2.0%)	51 (1.5%)

- An overall summary of TEAEs for subjects who wore the AG200-15 patch in the three Phase 3 studies is provided in (**Table 2**)
- There were no deaths among subjects who wore the patch
- Fewer than 2% of subjects had an SAE, and approximately 11% had TEAEs that resulted in study drug discontinuation
- The percentages of subjects with any TEAE, SAE, and TEAE resulting in study drug discontinuation in ATI-CL23 were comparable to those seen in the previous Phase 3 studies (ATI-CL12/13)

Table 2. Phase 3 Studies Summary of Treatment Emergent Adverse Events

	ATI-CL12/13		ATI-CL23	Overall
Cycles	1-6 (CL13) (N=1220)	1-13 (CL12) (N=1450)	1-13 (N=2031)	All (N=3481)
Subjects with Any TEAEs	580 (47.5%)	781 (53.4%)	1085 (53.4%)	1866 (53.6%)
Subjects with Any Study Drug-Related TEAEs	261 (21.4%)	338 (23.3%)	552 (27.2%)	890 (25.6%)
Subjects with Severe TEAEs	50 (4.1%)	73 (5.0%)	92 (4.5%)	165 (4.7%)
Subjects with SAEs	14 (1.2%)	16 (1.1%)	40 (2.0%)	56 (1.6%)
Subjects with Study Drug-Related SAEs	3 (0.3%)	3 (0.2%)	15 (0.7%)	18 (0.5%)
Subjects with TEAEs Resulting in Study Drug Discontinuation	119 (9.8%)	151 (10.4%)	224 (11.0%)	375 (10.8%)
Subjects Who Died	0	0	0	0

- Common TEAEs (i.e., those reported in at least 2% of subjects are summarized in (**Table 3**)
- Overall no individual TEAE was reported in > 6.0% of subjects
- In ATI-CL23, nasopharyngitis and upper respiratory tract infection were the two most frequently reported TEAEs; in ATI-CL12/13, nasopharyngitis and nausea were the two TEAEs most frequently reported
- Among the observed TEAEs, nausea, headache, cervical dysplasia, dysmenorrhea, and increase weight were considered potentially hormone-related TEAEs

Table 3. Phase 3 Studies Incidence of Most Common Treatment Emergent Adverse Events (≥ 2%)

	ATI-CL12/13		ATI-CL23	Overall
Cycles	1-6 (CL13) (N=1220)	1-13 (CL12) (N=1450)	1-13 (N=2031)	All (N=3481)
Nasopharyngitis	64 (5.3%)	83 (5.7%)	116 (5.7%)	199 (5.7%)
Upper respiratory tract infection	43 (3.5%)	55 (3.8%)	100 (4.9%)	155 (4.5%)
Nausea	50 (4.1%)	64 (4.4%)	84 (4.1%)	148 (4.3%)
Headache	41 (3.4%)	52 (3.6%)	72 (3.6%)	124 (3.6%)
Urinary tract infection	26 (2.1%)	48 (3.3%)	72 (3.6%)	120 (3.5%)
Cervical dysplasia	28 (2.3%)	90 (6.2%)	17 (0.8%)	107 (3.1%)
Sinusitis	35 (2.9%)	52 (3.6%)	54 (2.7%)	106 (3.1%)
Dysmenorrhea	22 (1.8%)	26 (1.8%)	47 (2.3%)	73 (2.1%)
Weight increased	23 (1.9%)	30 (2.0%)	41 (2.0%)	71 (2.0%)

Note: Preferred terms are coded using MedDRA version 18.1

- Overall 726 (20.9%) had TEAEs considered potentially hormone-related (**Table 4**)
- A total of 15.6% had a hormone-related TEAEs that were considered drug-related, 1.6% had a hormone-related severe TEAEs, 0.6% had a hormone related SAEs, and 5.3% had a hormone-related TEAEs that resulted in discontinuation of the study drug
- Application site skin irritation was the most frequently reported application site disorder and the application site disorder TEAE most frequently leading to discontinuation of study drug
- Subjects rated patch site skin irritation on a 4-point scale (0 = none, 1 = mild, 2 = moderate, 4 = severe)
- Across the safety population, for Cycles 1-13 combined, the subject-reported mean skin irritation score was 1.3

Table 4. Phase 3 Studies Potentially Hormone-Related TEAEs and Application Site Disorder Adverse Events (≥ 2% of Subjects) (N=3481)

Preferred Term	Any Hormone-Related TEAE	Severe TEAE	Drug Related TEAE	SAE	TEAE Resulting in Discontinuing Study Drug
Any Hormone-Related AE	726 (20.9%)	55 (1.6%)	543 (15.6%)	19 (0.6%)	183 (5.3%)
Nausea	148 (4.6%)	5 (0.1%)	103 (3.0%)	0	26 (0.8%)
Headache	124 (3.6%)	12 (0.3%)	75 (2.2%)	0	12 (0.3%)
Dysmenorrhea	73 (2.1%)	6 (0.2%)	56 (1.6%)	0	10 (0.3%)
Weight Increased	71 (2.0%)	2 (0.1%)	58 (1.7%)	0	9 (0.3%)
Application Site Disorder*	197 (5.7%)	24 (0.7%)	193 (5.5%)	0	125 (3.6%)
Application site irritation**	64 (1.8%)	6 (0.2%)	64 (1.8%)	0	52 (1.5%)

* A bundle of terms coded using MedDRA version 18.1

** Application site disorder TEAE most frequently reported by subjects

- Across all studies, 56 (1.6%) subjects reported SAEs
- Hormone related SAEs occurring in 19 subjects included cholelithiasis (4), deep vein thrombosis/embolism venous (4), pulmonary embolism (3), cholecystitis (3), major depression (3), suicidal ideation (2), suicide attempt (1), necrotizing pancreatitis (1), vomiting (1)
  - There were six women with venous thromboembolic events, five had baseline BMI ≥ 30 kg/m^2 and weight > 200 lbs
  - There were six women with cholelithiasis or cholecystitis, all had baseline BMI ≥ 35 kg/m^2 and weight > 210 lbs

CONCLUSION

- AG200-15 was generally well-tolerated and had an overall favorable safety profile
- The most-frequent hormone-related adverse events, none of which were experienced by more than 5% of subjects, were generally in line with adverse events observed in approved low dose combined hormonal products
- Overall, patch-related skin irritation was infrequent and was mild in severity
- Serious potentially hormone-related adverse events occurred in a population of women at higher baseline risk for these events (VTE and gallbladder disease)

Disclosures

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