

# AGILE THERAPEUTICS INC

## **FORM 8-K** (Current report filing)

Filed 09/29/17 for the Period Ending 09/28/17

Address	101 POOR FARM ROAD PRINCETON, NJ, 08540-1715
Telephone	609-683-1880
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(D)  
of the Securities Exchange Act of 1934**

**September 28, 2017**

Date of report (Date of earliest event reported)

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**Agile Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36464**  
(Commission  
File Number)

**23-2936302**  
(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)

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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

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.

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**Item 8.01. Other Events.**

On September 28, 2017, Agile Therapeutics, Inc. (“Agile”) a women’s healthcare company, announced that an abstract based on the Phase 3 SECURE trial of its investigational low-dose combination hormonal contraceptive patch (AG200-15) has been selected for a poster presentation during the North American Forum on Family Planning Annual Meeting being held October 14<sup>th</sup> — 16<sup>th</sup>, 2017 in Atlanta, GA. The abstract, titled “ *Bleeding And Spotting Results From The SECURE Trial: A Phase 3 Study Of The AG200-15 Investigational Transdermal Contraceptive Patch* ,” will be available in the October 2017 issue of *Contraception* or online at <http://www.contraceptionjournal.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.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Agile Therapeutics, Inc. Press Release dated September 28, 2017.</a>
99.2	<a href="#">Agile Therapeutics, Inc. Abstract dated September 28, 2017.</a>

**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 29, 2017

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

**Agile Therapeutics to Present Additional Phase 3 Data at the North American Forum on Family Planning Annual Meeting**

**PRINCETON, NJ, SEPTEMBER 28, 2017** - Agile Therapeutics, Inc., (NASDAQ:AGRX), a women's healthcare company, today announced that an abstract based on the Phase 3 SECURE trial of its investigational low-dose combination hormonal contraceptive patch (AG200-15) has been selected for a poster presentation during the North American Forum on Family Planning Annual Meeting being held October 14<sup>th</sup> — 16<sup>th</sup>, 2017 in Atlanta, GA. The abstract, titled "*Bleeding And Spotting Results From The SECURE Trial: A Phase 3 Study Of The AG200-15 Investigational Transdermal Contraceptive Patch*," will be available in the October 2017 issue of *Contraception* or online at <http://www.contraceptionjournal.org>.

The SECURE trial evaluated the clinical safety and efficacy of the investigational transdermal contraceptive patch AG200-15, known as Twirla<sup>®</sup>, in a diverse, real-world population of women reflective of current weight trends in the United States. The poster will focus on details of the AG200-15 bleeding profile that have not been previously reported.

**About Agile Therapeutics, Inc.**

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<sup>®</sup>, (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<sup>®</sup>, 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](http://www.agiletherapeutics.com). Follow Agile on Twitter: @agilether. The company may occasionally disseminate material, nonpublic information on the company website.

Source: Agile Therapeutics

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**Bleeding and spotting results from the SECURE Trial: a phase 3 study of the AG200-15 investigational transdermal contraceptive patch**

Anita L. Nelson(1),(2), Andrew M. Kaunitz(3), Robin Kroll(4), James A. Simon(5), Alfred N. Poindexter(6), Joseph A. Chiodo(7), Lisa Flood(7), Elizabeth I.O. Garner(7)

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(1)Western University of Health Sciences, Pomona, CA; (2)David Geffen School of Medicine at UCLA, Los Angeles, CA (Professor Emeritus); (3)University of Florida College of Medicine-Jacksonville, Jacksonville, FL; (4)University of Washington, Seattle, WA; (5)George Washington University School of Medicine, Washington, DC; (6)Baylor College of Medicine, Houston, TX; (7)Agile Therapeutics, Princeton, NJ

*Objectives:* To assess bleeding/spotting patterns during use of AG200-15 (levonorgestrel and ethinyl estradiol), an investigational weekly transdermal contraceptive patch.

*Methods:* This was a single-arm, open-label, 1-year (13-cycle), healthcare-company funded, Phase 3 IRB-approved study conducted at 102 US sites. Study subjects 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 2,017 women in the safety population provided 18,384 cycles of information on patterns of bleeding and spotting. Subject mean age was 27.5 years; mean weight was 76.1 kg (ranging from 39.0 to 176.9 kg). The mean number of scheduled bleeding-only days (bleeding on days when not wearing a patch) was  $2.7 \pm 2.08$  in Cycle 2 and decreased to  $2.3 \pm 1.97$  in Cycle 13, while the mean number of scheduled spotting-only days was  $1.0 \pm 1.25$  in Cycle 2 and decreased to  $0.9 \pm 1.27$  in Cycle 13. The mean number of unscheduled bleeding and/or spotting days was  $2.3 \pm 3.02$  in Cycle 2 and decreased to  $1.6 \pm 2.48$  in Cycle 13. The mean number of unscheduled bleeding-only days was  $1.4 \pm 2.24$  in Cycle 2 and decreased to  $1.0 \pm 1.75$  in Cycle 13, while the mean number of unscheduled spotting-only days was  $0.9 \pm 1.54$  in Cycle 2 and decreased to  $0.6 \pm 1.24$  in Cycle 13.

*Conclusions:* Bleeding/spotting patterns observed with the AG200-15 transdermal contraceptive patch are similar to patterns associated with currently marketed combination hormonal contraceptives and provide further support for the tolerability profile of AG200-15.

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