

# AGILE THERAPEUTICS INC

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

Filed 10/16/17 for the Period Ending 10/16/17

|             |   |
|-------------|---|
| Address     | 101 POOR FARM ROAD<br>PRINCETON, NJ, 08540-1715 |
| Telephone   | 609-683-1880                                    |
| CIK         | 0001261249                                      |
| Symbol      | AGRX  |
| SIC Code    | 2834 - Pharmaceutical Preparations              |
| Industry    | Biotechnology & Medical Research                |
| Sector      | Healthcare                                      |
| Fiscal Year | 12/31   |

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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**

**October 16, 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 October 16, 2017, Agile Therapeutics, Inc. (“Agile”) a women’s healthcare company, announced the presentation of additional results from the Phase 3 SECURE trial of its investigational low-dose combination hormonal contraceptive patch, Twirla® (AG200-15). Anita Nelson, MD, Professor and Chair of Obstetrics and Gynecology at the College of Osteopathic Medicine of the Pacific, presented new data on the Twirla bleeding profile during a poster presentation at the 2017 North American Forum on Family Planning (NAFFP), “The Forum” in Atlanta, GA.

Copies of Agile’s press release and poster presentation 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 October 16, 2017.</a>       |
| 99.2                  | <a href="#">Agile Therapeutics, Inc. Poster Presentation dated October 16, 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: October 16, 2017

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

**Agile Therapeutics Presents Additional Twirla® Phase 3 SECURE Study Results at NAFFP 2017***Detailed Bleeding Profile Data Provide Helpful Information for Patient Counseling*

**PRINCETON, N.J., Oct. 16, 2017** — Agile Therapeutics, Inc., (NASDAQ: AGRX), a women’s healthcare company, today announced the presentation of additional results from the Phase 3 SECURE trial of its investigational low-dose combination hormonal contraceptive patch, Twirla® (AG200-15). Anita Nelson, MD, Professor and Chair of Obstetrics and Gynecology at the College of Osteopathic Medicine of the Pacific, presented new data on the Twirla bleeding profile during a poster presentation at the 2017 North American Forum on Family Planning (NAFFP), “The Forum” in Atlanta, GA.

The poster presentation provided detailed analyses on scheduled (withdrawal) and unscheduled (breakthrough) bleeding and/or spotting episodes. Rates of unscheduled bleeding and/or spotting decreased during the study period. Similarly, the mean length of both unscheduled and scheduled bleeding and/or spotting episodes decreased during the study period. Few subjects discontinued from the trial for bleeding-related issues, and rates of unscheduled bleeding and/or spotting decreased over the 12-month study period.

The Phase 3 SECURE trial was a multicenter, single-arm, open-label, 13 cycle trial designed to evaluate the efficacy, safety and tolerability of Twirla in 2032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. Bleeding information was self-reported by subjects on a daily basis in electronic diaries. Subjects were asked about both scheduled and unscheduled bleeding and spotting, using definitions described by Mishell et al (Recommendations for Standardization of Data Collection and Analysis of Bleeding in Combined Hormone Contraceptive Trials; *Contraception* 75; 11-15 ).

Dr. Nelson commented, “The use of electronic diaries to collect daily bleeding data during the SECURE trial has yielded a robust package of data on the bleeding profile of Twirla. These new analyses provide information that will be very helpful to providers to guide counseling of patients considering use of the Twirla patch, if approved.”

For more information, please visit the company website at [www.agiletherapeutics.com](http://www.agiletherapeutics.com).

**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®, (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](http://www.agiletherapeutics.com). The company may occasionally disseminate material, nonpublic information on the company website.

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## **Forward-Looking Statement**

Certain information contained in this press release includes “forward-looking statements” related to the Company’s regulatory submissions. We may, in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involves risks, potential changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we may describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products; our statements about the planned resubmission of our NDA for Twirla could be affected by the potential that additional analyses of issues identified in our complete response letter from the FDA are required to be completed that were not previously anticipated, that our ongoing tests to support our resubmission are not completed on time, that the third parties we rely on to perform services in support of our NDA resubmission do not complete their work in a timely fashion and that other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review, and approval of Twirla by the FDA. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward-looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company’s Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Agile Therapeutics

### **Investor Relations Contact:**

Mary Coleman  
Agile Therapeutics  
609-356-1921

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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)

(1) Western University of Health Sciences, Pomona, CA; (2)David Geffen School of Medicine at UCLA (Professor Emeritus), Los Angeles, CA; (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

### Background

- AG200-15 (Twirla<sup>®</sup>) is a transdermal contraceptive delivery system designed to deliver daily doses of levonorgestrel (LNG) and ethinyl estradiol (EE) similar to oral doses of 120 µg of LNG and 30 µg of EE
- AG200-15 is under investigation as a once-weekly prescription contraceptive patch
- The SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) phase 3 trial examined the contraceptive efficacy, safety, and tolerability of AG200-15
- SECURE employed broad enrollment criteria with no restrictions based on body mass index (BMI) or weight
- The SECURE trial found that the Pearl Index for subjects age 18 to 35 years was 4.8 (upper bound of 95% confidence interval, 6.1) and adverse events (AEs) were comparable to approved combined hormonal contraceptives (Nelson et al., ACOG 2017)

### Objective

- To assess bleeding/spotting patterns during use of AG200-15

### Methods

- This single-arm, open-label, healthcare company-funded, multicenter, phase 3 study was conducted over a 1-year (13-cycle) period at 102 US sites
- This study was IRB-approved, and all patients provided informed consent
- Eligible subjects were women who were sexually active and who experienced regular menses every 21-38 days
- Subjects who were not currently using hormonal contraception were instructed to place the patch on the first day of bleeding (Cycle 1/Day 1)
- Subjects recorded information daily in electronic diaries (eDiaries) including but not limited to:
  - Bleeding, defined as evidence of blood loss requiring the use of sanitary protection with at least one tampon or sanitary pad
  - Spotting, defined as evidence of minimal blood loss requiring the use of pantyliners only or no sanitary protection
    - Subjects were instructed to record bleeding for any day during which they experienced both spotting and bleeding
  - Scheduled bleeding and/or spotting, occurring on days when not wearing a patch
  - Unscheduled bleeding and/or spotting, occurring on days when wearing a patch, except bleeding/spotting that began in the previous hormone-free period and continued through Days 1-4 of the new treatment cycle
- Study populations were defined as follows:
  - Cycle control population - all subjects who wore at least one patch, were documented to have a negative pregnancy test (serum β-hCG) at enrollment, and who provided information on bleeding and patch application in their eDiaries
  - Safety population - all subjects who wore at least one patch for any period of time regardless of age
- Safety assessments included the incidence of treatment-emergent adverse events (TEAEs), study discontinuation, and treatment-emergent changes in physical and gynecological examinations, vital signs, and clinical laboratory test results

## Results

- A total of 2031 women comprised the safety population; 2017 comprised the cycle control population (18,798 cycles)
- Subject mean age was 27.5 years; median weight was 71.9 kg (ranging from 39.0 to 176.9 kg) ( **Table 1** )

**Table 1. Demographics (Safety Population)**

|  | Overall<br>(n=2031) |
|--|---------------------|
| Age, y                                     |                     |
| Mean (SD)                                  | 27.5 (6.2)          |
| Median                                     | 26.0                |
| Min, Max                                   | 18, 60*             |
| ≤35, n (%)                                 | 1830 (90.1%)        |
| >35, n (%)                                 | 201 (9.9%)          |
| Race, n (%)                                |                     |
| Black/African American                     | 493 (24.3%)         |
| American Indian or Alaska Native           | 11 (0.5%)           |
| Asian                                      | 65 (3.2%)           |
| Native Hawaiian or Other Pacific Islander  | 8 (0.4%)            |
| White                                      | 1358 (66.9%)        |
| Other                                      | 96 (4.7%)           |
| Ethnicity, n (%)                           |                     |
| Hispanic or Latino                         | 400 (19.7%)         |
| Not Hispanic or Latino                     | 1631 (80.3%)        |
| Weight (kg)                                |                     |
| Mean (SD)                                  | 76.1 (20.4)         |
| Median                                     | 71.9                |
| Min, Max                                   | 39.0, 176.9         |
| BMI, kg/m <sup>2</sup>                     |                     |
| Mean (SD)                                  | 28.3 (7.1)          |
| Median                                     | 26.8                |
| Min, Max                                   | 15.1, 63.0          |
| BMI (kg/m <sup>2</sup> ) categories, n (%) |                     |
| Normal (<25)                               | 800 (39.4%)         |
| Overweight (≥25 to <30)                    | 513 (25.3%)         |
| Obese (≥30)                                | 717 (35.3%)         |
| Non-Obese (<30)                            | 1313 (64.7%)        |

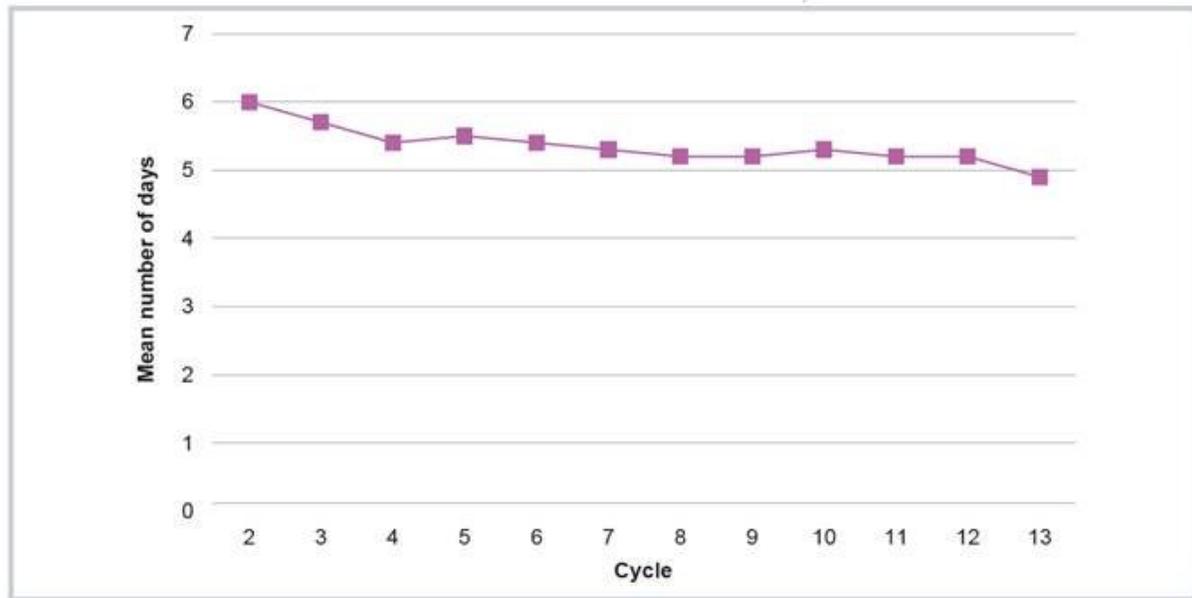
BMI, body mass index; SD, standard deviation.

\*One 60-year-old woman was enrolled but was discontinued shortly after.

### Bleeding and/or Spotting – Days

- The overall mean number of bleeding and/or spotting days, scheduled or unscheduled, was 6.0±4.05 in Cycle 2 and 4.9±3.5 in Cycle 13 ( **Figure 1** )

**Figure 1. Mean Number of Days of Bleeding and/or Spotting by Cycle (Cycle Control Population)**



- The percentage of subjects who reported no bleeding or spotting days in a cycle (amenorrhea) was 6.7% in Cycle 2 and 10.5% in Cycle 13 ( **Table 2** )

**Table 2. Subjects with No Bleeding or Spotting Days by Cycle (Cycle Control Population)**

| Cycle | Subjects<br>n/N (%) |
|-------|---------------------|
| 2     | 126/1875 (6.7%)     |
| 3     | 125/1745 (7.2%)     |
| 4     | 117/1627 (7.2%)     |
| 5     | 112/1519 (7.4%)     |
| 6     | 101/1428 (7.1%)     |
| 7     | 106/1351 (7.8%)     |
| 8     | 97/1277 (7.6%)      |
| 9     | 86/1213 (7.1%)      |
| 10    | 78/1143 (6.8%)      |
| 11    | 75/1103 (6.8%)      |
| 12    | 67/1065 (6.3%)      |
| 13    | 108/1024 (10.5%)    |

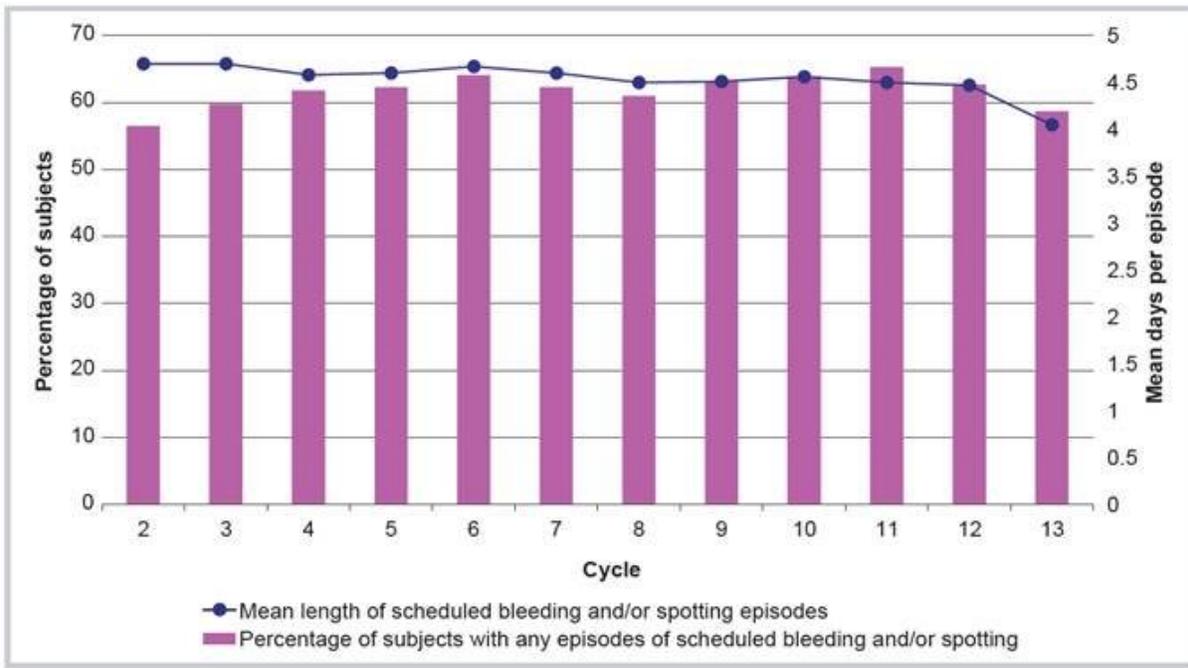
**Scheduled Bleeding and/or Spotting – Days**

- The mean number of scheduled bleeding and/or spotting days was 3.7±2.5 in Cycle 2 and 3.3±2.5 in Cycle 13
  - The mean number of scheduled bleeding-only days was 2.7±2.08 in Cycle 2 and 2.3±2.0 in Cycle 13
  - The mean number of scheduled spotting-only days was 1.0±1.3 in Cycle 2 and 0.9±1.3 in Cycle 13

**Scheduled Bleeding and/or Spotting – Episodes**

- In order to examine discrete incidents of bleeding and/or spotting, an episode was defined as one or more consecutive days of bleeding/spotting bounded on either end by  $\geq 2$  days of no bleeding or spotting
- Percentages of women experiencing at least 1 episode of scheduled bleeding and/or spotting by cycle are shown in **Figure 2**
  - The rate of women reporting at least 1 episode of scheduled bleeding and/or spotting was 56.5% in Cycle 2 and 58.7% in Cycle 13
- The mean length of scheduled bleeding and/or spotting episodes by cycle is shown in **Figure 2**
  - The mean length of scheduled bleeding and/or spotting episodes was 4.7 days in Cycle 2 and 4.1 days in Cycle 13
  - Episodes could have included individual days where no bleeding and/or spotting occurred since  $\geq 2$  days without bleeding or spotting were required to define the end of an episode

Figure 2. Scheduled Bleeding and/or Spotting Episodes by Cycle (Cycle Control Population)



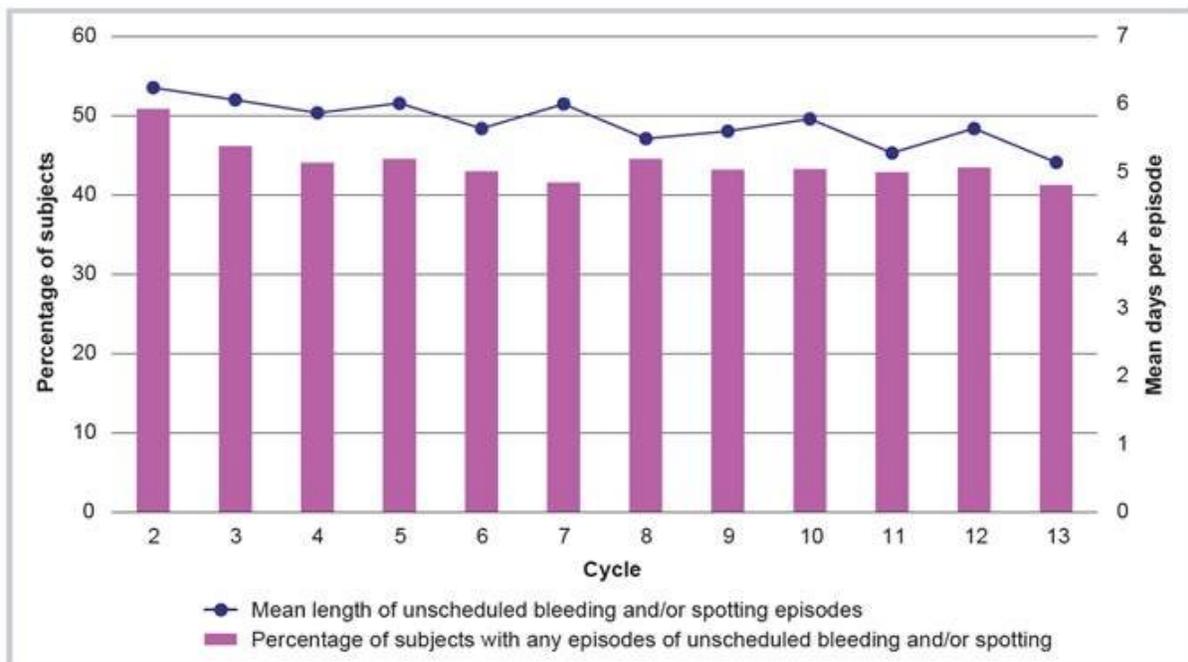
Unscheduled Bleeding and/or Spotting – Days

- The mean number of unscheduled bleeding and/or spotting days was  $2.3 \pm 3.0$  in Cycle 2 and  $1.6 \pm 2.5$  in Cycle 13
  - The mean number of unscheduled bleeding-only days was  $1.4 \pm 2.2$  in Cycle 2 and  $1.0 \pm 1.8$  in Cycle 13
  - The mean number of unscheduled spotting-only days was  $0.9 \pm 1.5$  in Cycle 2 and  $0.6 \pm 1.2$  in Cycle 13

Unscheduled Bleeding and/or Spotting – Episodes

- Percentages of women experiencing at least 1 episode of unscheduled bleeding and/or spotting by cycle are shown in **Figure 3**
  - The rate of women reporting at least 1 episode of unscheduled bleeding and/or spotting was 50.9% in Cycle 2 and 41.3% in Cycle 13
- The mean length of unscheduled bleeding and/or spotting episodes by cycle is shown in **Figure 3**
  - The mean length of unscheduled bleeding and/or spotting episodes was 6.3 days in Cycle 2 and 5.2 days in Cycle 13

Figure 3. Unscheduled Bleeding and/or Spotting Episodes by Cycle (Cycle Control Population)



## Safety

- Only 2.2% of women discontinued the study due to bleeding or spotting AEs, and 0.3% discontinued due to dysmenorrhea ( **Table 3** )

**Table 3. Treatment-Emergent Bleeding or Spotting AEs Leading to Study Drug Discontinuation (Safety Population)**

| Preferred Term  | Overall (n=2031) |
|---|------------------|
| <b>Any Treatment-Emergent Bleeding or Spotting AEs Leading to Drug Study Discontinuation*</b> | <b>45 (2.2%)</b> |
| Metrorrhagia  | 15 (0.7%)        |
| Vaginal hemorrhage  | 13 (0.6%)        |
| Menorrhagia   | 10 (0.5%)        |
| Dysmenorrhea  | 7 (0.3%)         |
| Dysfunctional uterine bleeding  | 2 (0.1%)         |
| Menstruation irregular  | 2 (0.1%)         |
| Menstrual disorder  | 1 (0.1%)         |

AEs, adverse events.

\*AEs are coded using MedDRA version 18.1.

## Conclusions

- In this diverse, real-world population of women, rates of scheduled bleeding and/or spotting episodes observed with the AG200-15 transdermal contraceptive patch were relatively stable
- Although inferential statistics were not performed, rates of unscheduled bleeding and/or spotting episodes numerically decreased during the study period
- Similarly, the mean length of both scheduled and unscheduled bleeding and/or spotting episodes showed numerical decreases during the study period
- Few subjects discontinued the study due to heavy/irregular vaginal bleeding
- These results provide information to guide patient counseling

## Disclosures

**AN:** Consultant/Advisor: Allergan, Agile, Bayer, ContraMed, Female Health, Merck, AMAG Pharma, Pharmanest; Honoraria/Speaker: Allergan, Aspen, Bayer, Merck, Teva; Grants/Research Support: Agile, ContraMed, Merck, Estetra SPRL, Evofem Inc.

**AK:** Consultant/Advisor: Allergan, Bayer, Merck, Mithra, Pfizer; Research Support (institution): Agile, Bayer, 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; Patent: No. 4,816,257 (embryo transplant).

**AP:** Consultant/Advisor: Agile, Allergan, Bayer, Pfizer.

**JC, LF, EG:** Employees: Agile Therapeutics.

## Acknowledgments

Funding to support the development this poster was provided by Agile Therapeutics to PharmaWrite, LLC (Princeton, NJ).



Presented at the North American Forum on Family Planning, October 14-16, 2017, Atlanta, Georgia