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 6, 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** (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:

☐ 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 2.02 Results of Operations and Financial Condition

On May 8, 2017, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2017 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On May 6, 2017, the Company announced the presentation of additional results of its Phase 3 SECURE clinical trial of its investigational low-dose combination hormone 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 a summary of SECURE clinical trial results, which included new data on the bleeding profile of clinical trial subjects during a poster presentation at the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG) in San Diego, California.

Dr. Nelson presented a summary of efficacy and safety results from the Company's SECURE clinical trial, which were previously reported in January 2017. The poster presentation also reported analyses on the bleeding profile, which demonstrated that unscheduled bleeding/spotting days per month decreased from a mean of 3.1 days in Cycle 1 to 1.6 days in Cycle 13. In addition, scheduled bleeding/spotting remained consistent during all cycles, with a reported mean of 3.1 to 3.7 days per month. Dr. Nelson also discussed the role of study designs and populations in contraceptive clinical trials.

Copies of the Company's press release and poster presentation are attached hereto as Exhibit 99.2 and 99.3, 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 May 8, 2017.
99.2	Agile Therapeutics, Inc. Press Release dated May 6, 2017.
99.3	Agile Therapeutics, Inc. Poster Presentation dated May 6, 2017.

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 8, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated May 8, 2017.
99.2	Agile Therapeutics, Inc. Press Release dated May 6, 2017.
99.3	Agile Therapeutics, Inc. Poster Presentation dated May 6, 2017

Exhibit 99.1

Agile Therapeutics Reports First Quarter 2017 Financial Results

Cash Expected to Fund Operations into Q2 2018

PRINCETON, New Jersey, May 8, 2017 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company today reported financial results for the three months ended March 31, 2017, and provided a corporate update for the first quarter 2017.

First quarter 2017 and other recent corporate developments include:

- **Twirla® Update** - In January 2017, the Company announced positive top-line results from its Phase 3 SECURE clinical trial of Twirla®, its investigational low-dose combined hormonal contraceptive patch. SECURE was a multicenter, single-arm, open-label, 13 cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2,032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. In April 2017, the Company announced it had received the final meeting minutes from its recent New Drug Application (NDA) pre-submission meeting with the U.S. Food and Drug Administration (FDA) for Twirla. Based on the feedback from the FDA, the Company believes it has the necessary information needed to complete the resubmission of its NDA, which is expected to be submitted by the end of the second quarter of 2017.

- **Medical Congress Updates** - In March 2017, the Company announced a poster presentation of data from the Phase 3 SECURE clinical trial for Twirla. The poster, titled "*The SECURE Study, a Real-World Trial of a Low-Dose Contraceptive Patch: Addressing the Changing U.S. Population,*" was presented at the Contraceptive Technology Conferences in San Francisco, CA and Boston, MA. The first author is Anita Nelson, MD, one of the co-primary investigators for the SECURE trial. On April 29, 2017, Dr. Anita Nelson presented "*An Update on Hormonal Contraception and The Changing U.S. Population*" at the Academy of Women's Health, and on May 6, 2017, the Company also presented an interactive ePoster session during the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists. The ePoster included efficacy and safety findings for the overall population and pre-specified body mass index categories in the SECURE clinical trial. The ePoster also included results on the bleeding profile of subjects in the SECURE trial that have not previously been reported.

- **Hercules Loan and Security Agreement Amendment —** In May 2017, the Company amended its loan and security agreement with Hercules Capital, Inc. (Hercules) to extend the period during which the Company may draw an additional tranche of $8.5 million until January 31, 2018 subject to the consent of Hercules.

"During the first quarter, we continued to advance towards our goal of receiving regulatory approval for Twirla, participated in a productive pre-submission meeting with the FDA and continued to prepare our NDA for resubmission. Additionally we have had multiple scientific opportunities to discuss our Phase 3 SECURE trial results at medical conferences. We continue to expect to submit our NDA by the end of the second quarter of 2017," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Additionally, we continue to focus on developing our commercialization plans in coordination with the prudent management of our capital resources. We believe that the flexibility built into our business plan can enable us to fund our operations into the second quarter of 2018."

First Quarter Financial Results

- **Cash and cash equivalents:** As of March 31, 2017, Agile had $41.7 million of cash and cash equivalents compared to $48.8 million of cash and cash equivalents as of December 31, 2016. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of March 31, 2017, will be sufficient to meet its operating requirements into the second quarter of 2018. The Company's current business plan assumes resubmission of the NDA for Twirla by the end of the second quarter of 2017, a six month FDA review of the Company's resubmission, initiation of pre-commercial activities and initiation of validation of its commercial manufacturing process in coordination with the commercialization of Twirla. The Company will require additional capital for the commercial launch of Twirla, if approved, as well as advancing the development of its other product candidates. In the event of unforeseen changes to its planned timelines, the Company has the ability to postpone certain commercial and validation spending that the Company believes will allow it to continue the funding of its operations into the second quarter of 2018.

- **Research and development (R&D) expenses:** R&D expenses were $4.7 million for the quarter ended March 31, 2017, compared to $4.9 million for the comparable period in 2016. The decrease in R&D expense was primarily due to decreased clinical development expenses as the Company's Phase 3 SECURE clinical trial for Twirla moved into the close-out phase. The decreased clinical development expenses were offset, in part, by expenses associated with commercial manufacturing scale-up activities.

- **General and administrative (G&A) expenses:** G&A expenses were $2.4 million for the quarter ended March 31, 2017, compared to $2.1 million for the comparable period in 2016. The increase in G&A expenses was primarily due to increased pre-commercialization activities.

- **Net loss:** Net loss was $7.5 million, or $0.26 per basic share for the quarter ended March 31, 2017, compared to a net loss of $7.3 million, or $0.27 per basic share for the quarter ended March 31, 2016.

- **Shares Outstanding:** At March 31, 2017, Agile had 28,776,398 shares of common stock outstanding.

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. The company may occasionally disseminate material, nonpublic information on the company website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials, regulatory submissions, projected cash position and potential market opportunity for its product candidates. 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

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statements are based on current beliefs and expectations of our management team that involve 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 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 our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute the Company's operational and budget plans, the FDA does not approve Twirla, the FDA's timeline for review is not completed within six months, our ability to timely complete the qualification and validation of our commercial manufacturing process, and unforeseen events in our clinical and manufacturing development plans; 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. 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

Contact: Mary Coleman — 609-356-1921

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)

(Unaudited)

	March 31, 2017	December 31, 2016

Assets		
Current assets:		
Cash and cash equivalents	$ 41,744	$ 48,750
Prepaid expenses	2,525	2,768
Total current assets	44,269	51,518
Property and equipment, net	12,330	12,330
Other assets	18	18
Total assets	$ 56,617	$ 63,866
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,749	$ 5,402
Loan payable, current portion	5,780	5,104
Warrant liability	63	172
Total current liabilities	11,592	10,678
Loan payable, long-term	9,416	10,899
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	236,590	235,754
Accumulated deficit	(200,984)	(193,468)
Total stockholders' equity	35,609	42,289
Total liabilities and stockholders' equity	$ 56,617	$ 63,866

Agile Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Operating expenses:		
Research and development	$ 4,721	$ 4,927
General and administrative	2,405	2,053
Total operating expenses	7,126	6,980
Loss from operations	(7,126)	(6,980)
Other income (expense)		
Interest expense, net	(499)	(531)
Change in fair value of warrants	109	193
Loss before benefit from income taxes	(7,516)	(7,318)
Benefit from income taxes	—	—
Net (loss) income	$ (7,516)	$ (7,318)
Net loss per share — basic and diluted	$ (0.26)	$ (0.27)
Weighted-average shares outstanding — basic and diluted	28,769,361	26,826,223

Exhibit 99.2

Agile Therapeutics Reports Additional Phase 3 SECURE Study Results Relating to Twirla® at ACOG 2017

Newly Reported Bleeding Profile Shows Reduction in Unscheduled Bleeding/Spotting Days

PRINCETON, NJ, MAY 6, 2017 — Agile Therapeutics, Inc., (NASDAQ: AGRX), a women's healthcare company, today announced the presentation of additional results of its Phase 3 SECURE trial of its investigational low-dose combination hormone 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 a summary of SECURE clinical trial results, which included new data on the bleeding profile of clinical trial subjects during a poster presentation at the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists (ACOG) in San Diego, CA.

Dr. Nelson presented a summary of efficacy and safety results from the company's SECURE clinical trial, which were previously reported in January 2017. The poster presentation also reported analyses on the bleeding profile, which demonstrated that unscheduled bleeding/spotting days per month decreased from a mean of 3.1 days in Cycle 1 to 1.6 days in Cycle 13. In addition, scheduled bleeding/spotting remained consistent during all cycles, with a reported mean of 3.1 to 3.7 days per month. Dr. Nelson also discussed the role of study designs and populations in contraceptive clinical trials.

"The SECURE trial was unique for its broad inclusion criteria and enrollment of diverse women with demographic backgrounds reflective of real-world settings", remarked Dr. Nelson. "It is important to provide women with a variety of contraceptive options and information so they can identify the hormonal combination and delivery method best suited to their needs and lifestyle."

The Phase 3 SECURE study was a multicenter, single-arm, open-label, 13 cycle trial designed to evaluate the efficacy, safety and tolerability of AG200-15, also known as Twirla, in 2032 healthy women, aged 18 years and over, at 102 investigational sites across the United States. The SECURE study design included a number of stringent elements, including exclusion of treatment cycles for use of back-up contraception and lack of sexual activity. The SECURE clinical trial also had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse patient population in order to allow efficacy to be assessed across different, real-world groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with a high BMI, who have frequently been underrepresented in past contraceptive studies.

Elizabeth Garner, MD, MPH, Chief Medical Officer of Agile Therapeutics, commented, "We are pleased with the results of the SECURE trial and believe our study may set a new standard for hormonal contraceptive studies. Our study entry criteria resulted in the inclusion of a real-world study population, including women who have frequently been underrepresented in past contraceptive studies. We believe the SECURE trial has generated valuable new data that will

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contribute to the evolving understanding of how co-morbidities such as obesity and other factors impact hormonal contraceptive effectiveness."

For more information, please visit the company website at 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. The company may occasionally disseminate material, nonpublic information on the company website.

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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

Media Relations Contact:
Glenn Silver
Lazar Partners Ltd.
646-871-8485
gsilver@lazarpartners.com

Exhibit 99.3

22A

Results From the SECURE Trial, a Phase 3 Study of the AG200-15 Investigational Transdermal Contraceptive Patch

Anita Nelson,[1,2] Andrew Kaunitz,[3] Robin Kroll,[4] James Simon,[5] Alfred Poindexter,[6] Joseph Chiodo,[7] Lisa Flood,[7] Elizabeth Garner[7]

[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

INTRODUCTION

- AG200-15 (Twirla®) is a transdermal contraceptive delivery system (TCDS) under investigation as a once-weekly prescription contraceptive patch
- AG200-15 is designed to deliver daily hormone exposure, as measured by area-under-the-curve (AUC) analyses, of ethinyl estradiol (EE) and levonorgestrel (LNG) that is similar to oral doses of 120 μg of LNG and 30 μg of EE
- The SECURE (Study to Evaluate Contraception Use, Reliability, and Effectiveness) was a 1-year, single-arm, open-label, multicenter phase 3 study of the contraceptive efficacy, safety and tolerability of AG200-15
- SECURE placed no limitations on body mass index (BMI) during enrollment
- We present selected efficacy and safety findings of the SECURE trial for the overall population and stratified by BMI

METHODS

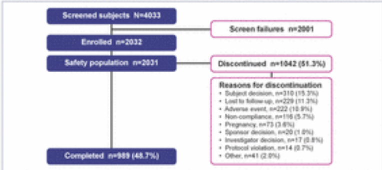
- The SECURE study enrolled sexually active female subjects at least 18 years of age who were at risk for pregnancy
- Subjects were excluded if they desired pregnancy within the next 12 months, were currently lactating, and/or anticipated or planned using condoms or emergency contraception or other forms of back-up contraception during the study, among other criteria
- Subjects recorded the following in electronic diaries: dates of patch application and patch change/removal, anatomic site of patch placement (lower abdomen, buttock, or upper torso), and reasons for any unscheduled patch changes; in addition, patch-related skin irritation and itching, patch adhesion, and assessment of bleeding or spotting were recorded daily
- Contraceptive Efficacy was assessed by the Pearl Index (PI) in subjects age 18-35 years old at study entry irrespective of BMI, excluding all cycles in which no intercourse occurred or other birth control methods (ie, back-up contraception) were used
- Contraceptive efficacy endpoints were also stratified by BMI
- Supportive life table efficacy analyses and patch wearability/tolerability measures were assessed
- Safety was assessed via collection of treatment emergent adverse events (TEAEs) in all subjects who wore at least one patch for any period of time

RESULTS

Subject Description at Baseline

- A total of 4033 women were screened and 2031 were included in the Safety population (**Figure 1**)

Figure 1: SECURE Subject Description


Screened subjects N=4033
Screen failures n=2001
Enrolled n=2032
Safety population n=2031
Discontinued n=1042 (51.3%)
Reasons for discontinuation
• Subject decision, n=310 (15.3%)
• Lost to follow-up, n=229 (11.3%)
• Adverse event, n=222 (10.9%)
• Non-compliance, n=116 (5.7%)
• Pregnancy, n=73 (3.6%)
• Sponsor decision, n=20 (1.0%)
• Investigator decision, n=17 (0.8%)
• Protocol violation, n=14 (0.7%)
• Other, n=41 (2.0%)
Completed n=989 (48.7%)

Demographic and Baseline Characteristics

- Enrolled women had a broad range of demographic and baseline characteristics
- A total of 1830 women were ≤35 years of age and 201 were >35 years of age
- Most women identified as White (66.9%) or African American (24.3%); in terms of ethnicity, 19.7% were Hispanic and 80.3% were non-Hispanic
- Approximately 35% of enrolled women had a BMI ≥30 kg/m² and 65% had a BMI <30 kg/m²
  - 800 women (39.4%) had a BMI <25 kg/m² (normal)
  - 513 women (25.3%) had a BMI ≥25 to <30 kg/m² (overweight)
  - 717 women (35.3%) had a BMI ≥30 kg/m² (obese)

Efficacy Analyses

- The PI for the overall ITT population of subjects ≤35 years of age was 4.80 with an upper-bound of the 95% confidence interval of 6.06
- Supportive life table analyses were performed and results for subjects ≤35 years of age are presented in **Table 1**

Table 1. Pregnancy Rates Based on Life Table Analysis in Women From Efficacy Population* (≤35 Years of Age)

Cycle	Number of Subjects	Number of On-Treatment Pregnancies	Probability of Pregnancy	95% CI
1	1816	3	0.17	0.05, 0.51
2	1681	11	0.64	0.35, 1.15
3	1556	17	1.02	0.64, 1.64
4	1448	26	1.64	1.12, 2.40
5	1349	31	2.00	1.41, 2.84
6	1263	39	2.62	1.92, 3.58
7	1192	41	2.79	2.06, 3.77
8	1130	46	3.22	2.41, 4.28
9	1068	48	3.40	2.56, 4.50
10	1004	49	3.49	2.64, 4.61
11	968	51	3.69	2.81, 4.85
12	930	53	3.90	2.98, 5.10
13	893	56	4.22	3.25, 5.48

*Subjects who wore at least one patch and had a negative enrollment serum β-hCG.

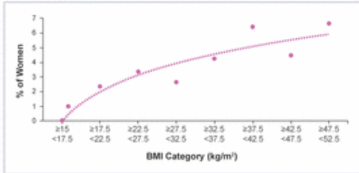
- A positive correlation was observed between BMI and % of subjects reporting pregnancies (**Table 2**, **Figure 2**)

Table 2. Pearl Index by BMI in Women From ITT Population* (≤35 Years of Age)

Parameter/Category	Pearl Index	Upper Bound of 95% CI
BMI (kg/m²)		
Normal (<25)	3.03	4.62
Overweight (≥25 to <30)	5.36	7.98
Non-obese (<30)	3.94	5.35
Obese (≥30)	6.42	8.88

*Includes all complete or incomplete on therapy cycles in which intercourse occurred and no back-up contraception was used.

Figure 2. Women From ITT Population ≥18 Years of Age Reporting Pregnancy, by BMI Category



Adverse Events

- The most frequent TEAEs known to be related to hormonal contraceptives are shown in **Table 3**

Table 3. The Most Frequent Treatment Emergent Adverse Events Commonly Attributed to Hormonal Contraceptives (Safety Population)

Parameter/Category	SECURE (n=2031)
Nausea	4.1%
Headache	3.6%
Mood swings/changes/depression[a]	2.8%
Breast tenderness/pain[b]	1.9%
Heavy and/or irregular vaginal bleeding[c]	1.8%

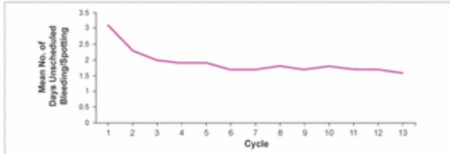
[a]MedDRA preferred terms = mood swings, depression, mood altered, major depression, and depressed mood; [b]MedDRA preferred terms = breast tenderness and breast pain; [c]MedDRA preferred terms = metrorrhagia, menorrhagia, menstruation irregular

- Serious adverse events (SAEs) were observed in 1.97% of subjects and included: cholelithiasis (n=4), deep vein thrombosis (n=3), pulmonary embolism (n=3), depression (n=3), gastroenteritis (n=2), cholecystitis (n=2), and ectopic pregnancy (n=2)

Bleeding/Spotting

- Women in the Safety population who provided information on bleeding (recorded daily) and patch application (Cycle Control population, n=2017) reported a mean number of scheduled bleeding/spotting days per month that ranged from 3 to 3.7 days during Cycles 1-13
- Women in the Cycle Control population reported a mean number of unscheduled bleeding/spotting days per month that generally decreased over the 13 cycles, declining from a mean of 3.1 days in Cycle 1 to a mean of 1.6 days in Cycle 13 (**Figure 3**)

Figure 3. Mean Number of Days of Unscheduled Bleeding and/or Spotting by Cycle (Cycle Control Population)



Continuations/Discontinuations

- A total of 989 (48.7%) women completed the study and used AG200-15 for up to thirteen 28-day cycles
- A total of 1042 (51.3%) women discontinued the study
- Reasons for discontinuation included subject decision (15.3%), loss to follow-up (11.3%), and adverse events (10.9%)
- The 3 most common AEs leading to discontinuation were application site irritation (1.1%), nausea (0.9%), and metrorrhagia (0.7%)

Wearability/Tolerability

- Of reported patches worn, 83% were associated with no patch site irritation and 65% with no itching
- Generally, the degree of reported irritation and itching was mild
- Severe itching or irritation were observed in 2.3% and 1.5% of patches worn, respectively
- Of reported patches worn, the rate of full detachment was 9.9% in Cycle 1 and 2.4% in Cycle 13

CONCLUSIONS

- The SECURE trial was conducted in a diverse, real-world population of women that reflects current obesity trends in the United States
- Overall PI and life table results from the SECURE trial suggest that AG200-15 is an important contraceptive option for women who prefer a non-daily hormonal method
- AG200-15 was well-tolerated and rates of hormone-related AEs were comparable to approved combined hormonal contraceptives
- Patch-related irritation and itching rates were low and the patch adhesion profile was favorable
- The SECURE trial has provided substantial new data on hormonal contraception effectiveness in women with BMIs ≥30 kg/m² and supports the hypothesis that, for short-acting combined hormonal contraceptives, obesity is associated with higher failure rates
- Additional analyses of clinical trial data are needed to understand not only the magnitude of the impact of obesity, but also to better understand why obese women experience higher contraception failure rates

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DISCLOSURES

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

JC, LF, EG: Employees, Agile Therapeutics.

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