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

January 3, 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:

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))

Item 8.01. Other Events.

On January 3, 2017, Agile Therapeutics, Inc. (the "Company") issued a press release announcing 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 2032 healthy women aged 18 and over at 102 experienced investigative sites across the United States. The Company plans to resubmit its new drug application ("NDA") for Twirla in the first half of 2017 on the basis of the SECURE results and other information relating to the manufacture of Twirla.

The Company will also host a conference call to discuss the top-line results from the SECURE clinical trial on January 3, 2017. A copy of the conference call presentation materials is also attached hereto as Exhibit 99.2.

Top-line data are based on a preliminary analysis of currently available efficacy and safety data, and therefore the reported results, findings and conclusions related to SECURE are subject to change following a comprehensive review of the complete data related to SECURE.

SECURE was conducted to address issues raised by the U.S. Food and Drug Administration ("FDA") in its 2013 Complete Response Letter ("CRL") to the Company. The CRL recommended that the Company conduct a new clinical trial and focused on two key elements: improved clinical trial conduct and

demonstration of efficacy as measured by an acceptable Pearl Index and related 95% confidence interval in a representative sample of U.S. women who are seeking hormonal contraception, including elements such as contraceptive user status, age, race, ethnicity, and body mass index ("BMI"). The trial was designed in consultation with the FDA, and comprised a number of stringent trial design elements, including exclusion of treatment cycles not only for use of back-up contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with high BMI, who have frequently been under-represented in past contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent to treat population of subjects 35 years of age and under. The FDA also requested inclusion of pre-specified efficacy analyses related to BMI and body weight.

Highlights of the top-line results include:

- Consistent with its broad entry criteria, the SECURE study population was representative of the population of women in the United States with respect to key demographic criteria, including:
  - Race (66.9% of subjects were white, 24.3% black and 8.8% other);
  - Ethnicity (19.7% were Hispanic, 80.3% non-Hispanic); and

  - BMI (39.4% of subjects had a normal baseline weight (BMI of under 25 kg/m^2), 25.3% of subjects were overweight (BMI of at least 25 kg/m^2 but less than 30 kg/m^2), and 35.3% were obese (BMI 30 kg/m^2 or more). When classified as obese (BMI 30 kg/m^2 or more) or non-obese (BMI less than 30 kg/m^2), 35.3% of subjects were obese and 64.7% were non-obese).
- Both new and experienced hormonal contraceptive users were enrolled (9.4% of subjects were new users).
- 51.4% of subjects discontinued prematurely from the study and the loss to follow-up rate was 11.3%, which is in line with loss to follow-up rates observed in previous clinical trials of combined hormonal products and substantially better than the 20% loss to follow-up rate observed in the Company's previous Phase 3 trial.
- The Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06. As with all hormonal contraceptive trials, the number of pregnancies included in the Company's calculation of the Pearl Index is subject to review by the FDA as part of its overall review of the NDA for Twirla.
- Consistent with other recent hormonal contraceptive clinical trials, including Ortho Evra® and Quartette®, and the FDA's 2015 meta-analysis on the effect of obesity on the effectiveness of hormonal contraceptives, a relationship between obesity and efficacy was observed among subjects 35 years of age and under:

BMI Category	BMI (kg/m^2)	% of Trial Population	Pearl Index	Upper Bound of 95% CI
Normal	< 25	39%	3.03	4.62
Overweight	25 - < 30	25%	5.36	7.98
Obese*	≥ 30	35%	6.42	8.88
Non-Obese*	< 30	65%	3.94	5.35
Obese*	≥ 30	35%	6.42	8.88

*In its 2015 meta-analysis, the FDA examined the effect of obesity on two populations: non-obese (< 30 kg/m^2) and obese (≥ 30 kg/m^2). Non-obese includes subjects in the normal and overweight categories.

- The highest Pearl Index for a hormonal contraceptive product approved by the FDA was 3.19 with an upper-bound of the 95% confidence interval of 5.03. As with all products, ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index. For hormonal contraceptive trials, the FDA generally evaluates efficacy results of each individual study in the unique context of the study population and trial design.

- Twirla was generally well tolerated and had an overall favorable safety profile, consistent with publicly available information relating to other low-dose combined hormonal products. The most frequent hormone-related adverse events, none of which were experienced by more than 5% of subjects, were generally in line with those events observed in other low dose combined hormonal products and included:

Adverse Event	SECURE (n=2032)
Headache	4.3%
Nausea	4.1%
Breast tenderness/pain/discomfort	2.0%
Mood swings/changes/depression	2.7%
Heavy/irregular vaginal bleeding	1.8%

- The percent of subjects reporting bleeding-related adverse events was low, 1.8%, and only 1.4% of women discontinued for bleeding issues.

- Serious adverse events were observed in 1.7% of subjects. The most common serious adverse events included deep vein thrombosis, pulmonary embolism, gallbladder disease, ectopic pregnancy and depression.

- Overall, patch-related irritation and itching rates were low. Of reported patches worn, 83% had no patch site irritation and 65% had no itching. Generally, reported irritation and itching was mild. Severe itching or irritation were observed in 2.3% and 1.5% of patches worn, respectively.

- The patch adhesion profile was favorable with a low rate of detachment. Of reported patches worn, the range of detachments was 10% in cycle 1 and reduced to 2% by cycle 13.

The Company will also host a conference call to discuss the top-line results from the SECURE clinical trial on January 3, 2017.

Copies of the Company's press release and the conference call presentation materials are attached hereto as Exhibits 99.1 and 99.2, respectively, and are hereby incorporated by reference herein.

Risks Related to the Reported Results of SECURE

The reported results of SECURE are based on top-line data and may ultimately differ from actual results once additional data are received and fully evaluated.

The reported results of SECURE that we have publicly disclosed, and that are discussed herein, consist of top-line data. Top-line data are based on a preliminary analysis of currently available efficacy and safety data, and therefore the reported results, findings and conclusions related to SECURE are subject to change following a comprehensive review of the more extensive data that

we expect to receive related to SECURE. Top-line data are based on important assumptions, estimations, calculations and information currently available to us, and we have not received or had an opportunity to fully and carefully evaluate all of the data related to SECURE. As a result, the top-line results of SECURE that we have reported may differ from future results, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the potential for approval of Twirla, or if approved, the labeling and commercial value of Twirla and our business in general. If the top-line data that we have reported related to SECURE differ from actual results, our ability to obtain approval for, and commercialize, our products may be harmed, which could harm our business, financial condition, operating results or prospects.

The FDA may disagree with our interpretation of clinical results obtained from SECURE, our results do not guarantee support for a resubmission of our NDA or for regulatory approval, and, even if the SECURE data are deemed to be positive by the FDA, the FDA may disagree with other aspects of the SECURE study and decline to approve Twirla for the proposed indication.

We have reported positive top-line data from SECURE. However, even if we believe that the data from SECURE are positive, the FDA could determine that the data from SECURE were negative or inconclusive or could reach a different conclusion than we did on that same data. Negative or inconclusive results of a clinical trial or difference of opinion could cause the FDA to decline to approve our application or require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results to the satisfaction of the FDA or that the FDA will agree with our interpretation of the results. Any such determination by the FDA would delay the timing of our commercialization plan for Twirla or prevent its further development, or the further development of our other product candidates, and adversely affect our business operations. Additionally, the FDA may provide review commentary at any time during the resubmission and review process which could delay the review timeline, adversely affect the review process, or even prevent the approval of Twirla, any of which would adversely affect our business. We may not be able to appropriately remedy issues that the FDA may raise in its review of our NDA resubmission, and we may not have sufficient time or financial resources to conduct future activities to remediate issues raised by the FDA.

There is no guarantee that the data obtained from SECURE will be supportive of, or guarantee, an NDA resubmission, or result in our successfully obtaining FDA approval of Twirla in a timely fashion and for a commercially viable indication, if at all. For example, the FDA could determine that the trial did not meet its objectives or the FDA could still have concerns regarding the conduct of the SECURE study, including regarding discontinuance of subjects from the trial. At any future point in time, the FDA could require us to complete further clinical or preclinical trials, or take other actions which could delay or preclude any NDA resubmission or approval of the NDA and could require us to obtain significant additional funding. There is no guarantee such funding would be available to us on favorable terms, if at all, nor is there any guarantee that FDA would consider any additional information complete or sufficient to support approval. If the Twirla NDA is resubmitted, the FDA may hold an advisory committee meeting to obtain committee input on the

safety and efficacy of Twirla. Typically, advisory committees will provide responses to specific questions asked by the FDA, including the committee's view on the approvability of the product candidate under review. Advisory committee decisions are not binding but an adverse decision at the advisory committee may have a negative impact on the regulatory review of Twirla. Additionally, we may choose to engage in the dispute resolution process with the FDA if we do not receive approval, which could extend the timeline for any potential approval.

Further, if we are able to resubmit an NDA for Twirla with the clinical data from SECURE, there is no guarantee that such data will be deemed sufficient by the FDA. While we designed the protocols for SECURE to address the issues raised in the CRL, there is no guarantee that the FDA will deem such protocols or results from the study sufficient to address those issues when they are formally reviewed as a part of an NDA resubmission or to demonstrate safety and efficacy to the satisfaction of the FDA. The FDA has significant discretion in the review process, and we cannot predict whether the FDA will agree with our conclusions regarding the results of the SECURE trial, including whether our data are reliable and generalizable. For example, the FDA may disagree with our calculations relating to the number of pregnancies occurring on study, or may view the SECURE data as insufficient to demonstrate a favorable benefit/risk profile for approval for the proposed indication. In addition, based on top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years

of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. If we were to exclude the top-line data on the obese subpopulation, our Pearl Index for non-obese patients was 3.94 with an upper-bound of the 95% confidence interval of 5.35. The highest Pearl Index for a hormonal contraceptive product approved by the FDA was 3.19 with an upper-bound of the 95% confidence interval of 5.03. Although ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that our Pearl Index for either the overall study population or only the non-obese study population is too high to demonstrate efficacy and an adequate risk/benefit profile, and as such, the FDA could decline to approve Twirla on this or any other basis. Further, the FDA may not agree with our analysis of the relationship between obesity and efficacy for Twirla and the FDA may interpret our overall data differently than we do and may decline to approve Twirla on this or any other basis.

Moreover, even if we obtain approval of Twirla, any such approval might significantly limit the approved indications for use, including by limiting the approved label for use by more limited patient populations than we propose, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies, or REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of Twirla. For example, the FDA may deem the higher Pearl Index in the obese subpopulation to warrant a labeling limitation or warning for such subpopulation, which could limit the commercial potential of the product, if approved. Moreover, because we did not conduct any head-to-head studies of Twirla against Ortho Evra®, we will not be able to make direct comparative claims regarding the safety, efficacy or pharmacokinetics of Twirla and Ortho Evra or its generic version, Xulane®.

We are substantially dependent on the commercial success of Twirla.

If we obtain FDA approval of Twirla, Twirla will be the first product that we commercialize. The rest of our pipeline of products are in earlier stages of clinical development and will require additional clinical and product development and funding in order to advance towards commercialization, which could take considerable time. If Twirla is not approved, our ability to advance our pipeline would be significantly adversely affected. Our ability to generate revenues

and become profitable will depend in large part on the commercial success of Twirla. If Twirla or any other product that we commercialize in the future does not gain an adequate level of acceptance among physicians, patients and third parties, we may not generate significant product revenues or become profitable. Market acceptance of Twirla, and any other product that we commercialize, by physicians, patients and third party payors will depend on a number of factors, some of which are beyond our control, including:

- Efficacy, safety and other potential advantages of our product candidates in relation to alternative treatments;
- Relative convenience and ease of administration of our product candidates;
- Availability of adequate coverage or reimbursement of our product candidates by third parties, such as insurance companies and other payors, and by government healthcare programs, including Medicare, Medicaid and state health insurance exchanges;
- Prevalence and severity of adverse events associated with our product candidates;
- Cost of our product candidates in relation to alternative treatments, including generic products;
- Extent and strength of our third-party manufacturer and supplier support;
- Extent and strength of our marketing and distribution support;
- Limitations or warnings contained in our product's FDA approved labeling; and
- Distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan.

For example, if Twirla is approved by the FDA, physicians and patients may not be immediately receptive to a transdermal contraceptive system, as opposed to a pill or any other method, and may be slow to adopt it as an accepted treatment for the prevention of pregnancy. In addition, even though we believe Twirla has the potential to offer significant advantages over other treatment options, because no head-to-head trials comparing Twirla to the competing approved patch product have been conducted, the prescribing information approved by the FDA may not contain claims that Twirla is safer or more effective than the currently approved patch product, or other claims that may be necessary for successful marketing of Twirla. Accordingly, we will not be permitted to promote Twirla, if approved, for any comparative advantages to the currently marketed contraceptive patch. The availability of numerous inexpensive generic forms of contraceptive products may also limit acceptance of Twirla among physicians, patients and third party payors. If Twirla does not achieve an adequate level of acceptance among physicians, patients and third party payors, we may not generate significant product revenues or become profitable.

Even if we obtain marketing approval for Twirla or other product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Twirla or other product candidates could be subject to labeling and other restrictions, including withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems.

Even if we obtain U.S. regulatory approval of Twirla or other product candidates, the FDA may still impose significant restrictions on their indicated uses, including more limited patient populations, require that precautions, contraindications, or warnings be included on the product labeling, including black box warnings, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Claims that we may make may also be restricted through our approved labeling. For example, based on the

SECURE top-line data, the Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06, but in the obese subpopulation of subjects 35 years of age and under, the Pearl Index was 6.42 with an upper-bound of the 95% confidence interval of 8.88. The highest Pearl Index for a hormonal contraceptive product approved by the FDA was 3.19 with an upper-bound of the 95% confidence interval of 5.03. Although ultimate approvability of a hormonal contraceptive is based on a risk/benefit assessment of the overall safety and efficacy profile of a product, not only a specific Pearl Index, the FDA could conclude that the Pearl Index in the obese subpopulation is too high to demonstrate efficacy and an adequate risk/benefit profile. As such, even if we receive approval of Twirla, the FDA could impose restrictions on use by the obese subpopulation or otherwise require labeling limitations or warnings for such subpopulation, which could limit the commercial potential of the product, if approved.

If approved, Twirla and our other product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, import, export, safety surveillance, advertising, marketing promotion, recordkeeping, reporting of adverse events and other post-market information, and further development. These requirements include registration with the FDA, listing of our drug products, payment of annual fees, as well as continued compliance with current Good Clinical Practices ("cGCPs") for any clinical trials that we conduct post approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices ("cGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we are found to be noncompliant with applicable requirements, the FDA and other government authorities may issue a Warning Letter or Untitled Letter, or take other regulatory action such as a product seizure and detention, withdrawal of product approval, request for a recall, refusal to allow the import or export of the product, criminal or civil penalties, injunction against or restriction of manufacture or distribution, consent decrees, disgorgement, restitution, clinical holds or terminations, exclusion from federal healthcare programs, corporate integrity agreements, or imprisonment.

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, expectations regarding the clinical significance and regulatory review of top-line data from our Phase 3 SECURE study and the timing of resubmission of our NDA for Twirla.

The Company 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 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 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 Current Report on Form 8-K. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated January 3, 2017.
99.2	Agile Therapeutics, Inc. Presentation on SECURE Top-Line Results

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: January 3, 2017

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

Exhibit 99.1

Agile Therapeutics Announces Positive Top-line Phase 3 Results

Resubmission of Twirla® New Drug Application Expected to Address FDA's Complete Response Letter

Company Plans to Resubmit NDA in First Half of 2017

Company to Host Conference Call on January 3, 2017 at 5:00 p.m. Eastern Time

Princeton, New Jersey, January 3, 2017 — Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's health specialty pharmaceutical company, today 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 2032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The Company plans to resubmit its new drug application ("NDA") for Twirla in the first half of 2017 on the basis of the SECURE results and other information relating to the manufacture of Twirla.

SECURE was conducted to address issues raised by the U.S. Food and Drug Administration ("FDA") in its 2013 Complete Response Letter ("CRL") to the Company. The CRL recommended that the Company conduct a new clinical trial and focused on two key elements: improved clinical trial conduct and demonstration of efficacy as measured by an acceptable Pearl Index and related 95% confidence interval in a representative sample of U.S. women who are seeking hormonal contraception, including elements such as contraceptive user status, age, race, ethnicity, and body mass index ("BMI"). The trial was designed in consultation with the FDA, and comprised a number of stringent trial design elements, including exclusion of treatment cycles not only for use of back-up contraception but also for lack of sexual activity. SECURE had broad entry criteria, placed no limitations on BMI or other demographic factors during enrollment, and enrolled a large and diverse population from the United States in order to allow for efficacy to be assessed across different groups, as requested by the FDA. These entry criteria resulted in the inclusion of a substantial number of women with high BMI, who have frequently been under-represented in past contraceptive studies. The efficacy measure for SECURE was the Pearl Index in an intent to treat population of subjects 35 years of age and under. The FDA also requested inclusion of pre-specified efficacy analyses related to BMI and body weight.

Highlights of the top-line results include:

- Consistent with its broad entry criteria, the SECURE study population was representative of the population of women in the United States with respect to key demographic criteria, including:
  - Race (66.9% of subjects were white, 24.3% black and 8.8% other);
  - Ethnicity (19.7% were Hispanic, 80.3% non-Hispanic); and
  - BMI (39.4% of subjects had a normal baseline weight (BMI of under 25 kg/m^2), 25.3% of subjects were overweight (BMI of at least 25 kg/m^2 but less than 30 kg/m^2), and 35.3% were obese (BMI 30 kg/m^2 or more). When classified as obese (BMI 30 kg/m^2 or more) or non-obese (BMI less than 30 kg/m^2), 35.3% of subjects were obese and 64.7% were non-obese).
- Both new and experienced hormonal contraceptive users were enrolled (9.4% of subjects were new users).
- 51.4% of subjects discontinued prematurely from the study and the loss to follow-up rate was 11.3%, which is in line with loss to follow-up rates observed in previous clinical trials of combined hormonal products and substantially better than the 20% loss to follow-up rate observed in the Company's previous Phase 3 trial.
- The Pearl Index for the overall intent to treat population of subjects 35 years of age and under was 4.80 with an upper-bound of the 95% confidence interval of 6.06. As with all hormonal contraceptive trials, the

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number of pregnancies included in Agile's calculation of the Pearl Index is subject to review by the FDA as part of its overall review of the NDA for Twirla.

- Consistent with other recent hormonal contraceptive clinical trials, including Ortho Evra® and Quartette®, and the FDA's 2015 meta-analysis on the effect of obesity on the effectiveness of hormonal contraceptives, a relationship between obesity and efficacy was observed among subjects 35 years of age and under:

BMI Category	BMI (kg/m^2)	% of Trial Population	Pearl Index	Upper Bound of 95% CI
Normal	< 25	39%	3.03	4.62
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Obese*	≥ 30	35%	6.42	8.88
Non-Obese*	< 30	65%	3.94	5.35
Obese*	≥ 30	35%	6.42	8.88

*In its 2015 meta-analysis, the FDA examined the effect of obesity on two populations: non-obese (< 30 kg/m^2) and obese (≥ 30 kg/m^2). Non-obese includes subjects in the normal and overweight categories.

- Twirla was generally well tolerated and had an overall favorable safety profile, consistent with publicly available information relating to other low-dose combined hormonal products. The most frequent hormone-related adverse events, none of which were experienced by more than 5% of subjects, were generally in line with those events observed in other low dose combined hormonal products and included:

Adverse Event	SECURE (n=2032)
Headache	4.3%
Nausea	4.1%
Breast tenderness/pain/discomfort	2.0%
Mood swings/changes/depression	2.7%

Heavy/irregular vaginal bleeding	1.8%

- The percent of subjects reporting bleeding-related adverse events was low, 1.8%, and only 1.4% of women discontinued for bleeding issues.
- Serious adverse events were observed in 1.7% of subjects. The most common serious adverse events included deep vein thrombosis, pulmonary embolism, gallbladder disease, ectopic pregnancy and depression.
- Overall, patch-related irritation and itching rates were low. Of reported patches worn, 83% had no patch site irritation and 65% had no itching. Generally, reported irritation and itching was mild. Severe itching or irritation were observed in 2.3% and 1.5% of patches worn, respectively.
- The patch adhesion profile was favorable with a low rate of detachment. Of reported patches worn, the range of detachments was 10% in cycle 1 and reduced to 2% by cycle 13.

“We have now successfully completed our clinical trials for Twirla and added substantial clinical data to our existing body of information, in particular around the safety profile for the patch. SECURE represented an excellent opportunity to further examine the safety and effectiveness of Twirla in a trial designed to meet the FDA’s recommendations for current contraceptive studies and focused on improved study conduct,” said Dr. Elizabeth Garner, Senior Vice-President and Chief Medical Officer of Agile. “We believe we have addressed the clinical

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questions raised by the FDA in its CRL, and also produced important public health data in obese women that the FDA called for in its 2015 publication. We look forward to discussing these topics with the Agency. We greatly appreciate the hard work and dedication from our clinical team and wish to thank the clinical investigators, their staff, and most importantly, the 2032 women who participated in the SECURE trial.”

Based on the results from the SECURE trial, Agile plans to prepare its response to the FDA’s CRL, which will also include information relating to the manufacture of Twirla requested by the FDA. The Company plans to resubmit its NDA to the FDA in the first half of 2017.

“We are very pleased with having achieved this critical milestone for Agile” said Al Altomari, President and Chief Executive Officer of Agile. “Now that we have successfully completed SECURE, we are focused on preparing the resubmission of our NDA and continuing our progress towards seeking approval of Twirla and commercializing Twirla in the United States”

The Company also re-affirmed that based on its current business plan, it believes its cash and cash equivalents will be sufficient to meet its operating requirements through the end of 2017.

Additional information on the SECURE clinical trial is available at www.clinicaltrials.gov.

Company to Host Conference Call

Agile Therapeutics will host a conference call with slides today, January 3, 2017, at 5:00 p.m. Eastern Time to discuss the Company’s results from the SECURE clinical trial. A question and answer session will follow Agile Therapeutics’ remarks. To participate on the live call, please dial (844) 413-1773 (domestic) or (678) 865-8976 (international), and provide the conference ID 46605850, approximately five to 10 minutes ahead of the start of the call.

A live audio webcast of the call and accompanying slides will be available via the “Investor Relations” page of the Agile Therapeutics website, www.agiletherapeutics.com. Please log on through Agile Therapeutics’ website approximately 10 minutes prior to the scheduled start time. A replay of the webcast and accompanying slides will be archived on Agile Therapeutics’ website for 60 days following the call.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women’s health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. 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 adherence and patient acceptability. For more

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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 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 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 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.

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Source: Agile Therapeutics

Contact: Mary Coleman — 609-356-1921

Agile Announces Positive Top-line Phase 3 Results for Twirla®

Agile® THERAPEUTICS

SECURE Conference Call and Webcast

January 3, 2017

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials, regulatory submissions 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.

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Agenda

- **Introduction**
  - Presented by Agile Chief Executive Officer, Al Altomari
- **Top-line Results**
  - Presented by Agile Chief Medical Officer, Elizabeth Garner, M.D., M.P.H.
    - Study Design and Top-line Results
    - Basis for resubmission
- **Concluding Remarks**

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The CRL Expressed a Clear Rationale for a New Study

Focused on two key elements

- **Improved study conduct**
  - Reduced loss to follow-up rate compared to previous Phase 3 trials
  - Support subject compliance and overall retention
- **Demonstration of acceptable efficacy in a representative population**
  - "An acceptable Pearl Index and upper bound of the 95% confidence interval"
  - "A representative sample of women in the U.S. who are seeking hormonal contraception"
  - "A sufficiently large and diverse population so that efficacy can be assessed in subgroups"

Quotes sourced from FDA correspondence

CRL = Complete Response Letter
FDA = Food & Drug Administration

The SECURE Trial Was Designed to Assess the Efficacy and Safety of Twirla® in a Real-World Population

Rigorous trial design was focused on key elements of the CRL

- **Multicenter, single-arm, open-label 13-cycle trial at 102 experienced U.S. clinical sites**
  - ~ 2,000 healthy subjects aged ≥ 18 treated with laser-etched patches
- **Representative sample of women seeking hormonal contraception**
  - No exclusions for BMI/weight
- **Stringent Trial Design**
  - Frequent pregnancy testing
  - Exclusion of cycles for BOTH use of back-up contraception and lack of sexual activity
- **Analysis**
  - Efficacy measure was Pearl Index in an ITT population of subjects 35 years of age and under
  - Prespecified analysis related to BMI and body weight

CRL = Complete Response Letter
ITT = Intent to Treat

Demographics Reflect the Broad Entry Criteria of the SECURE Trial

Study	SECURE	Ortho Evra Trials	Quartette Trial
Age			
Mean age	28 years	28 years	27 years
≤ 35 years	90%	83%	90%
> 35	10%	17%	10%
Body Mass Index			
Mean BMI*	28.3 kg/m^2	23.6 kg/m^2	27.4 kg/m^2
< 25 (normal)	39%	Not available	47%
25 - < 30 (overweight)	25%		25%
≥ 30 (obese)	35%		28%
Race			
White	67%	91%	64%
Black	24%	5%	19%
Asian	3%	2%	2%
Other	6%	2%	14%
Ethnicity			
Hispanic	20%	Not available	11%
Non-Hispanic	80%		89%
Hormonal Contraception Use			
Current user	35%	Not available	44%
Recent user	13%		
Former user	43%		39%
New user	9%		17%

Percentages in table are rounded to nearest integer; may not add up to 100%

*Based on CDC BMI categories

Information is based on currently marketed Ortho Evra and Quartette product labels and publicly available information. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.

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SECURE Achieved a Lower Loss to Follow-Up Rate

Loss to follow-up rate substantially reduced compared to prior Agile Phase 3 trial, and in line with other contraceptive trials

	SECURE		Agile Prior Phase 3*		Quartette†	
Metric	n	%	n	%	n	%
Enrolled	2032	100.0	1129	100.0	3597	100.0
Discontinued**	1043	51.4	644	57.0	1453	40.3
Lost to Follow-up	229	11.3	229	20.3	480	13.3
Completed	988	48.6	485	43.0	2144	59.6

**Main reasons for subject discontinuation from SECURE trial: subject decision, adverse event, loss to follow-up

†Information is based on currently marketed Quartette product label and publicly available information. We have not performed a head-to-head comparison of Twirla to Quartette.

**Includes only subjects originally randomized to patch arm*

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Positive Evidence of Efficacy in a Real-World Population

A tight confidence interval was achieved on the overall results

Population (ITT)	Pearl Index	UB 95% CI
≤ 35 years of age	4.80	6.06

An effect of obesity was observed

BMI Category	BMI (kg/m^2)	% of Study Population	Pearl Index	UB 95% CI
Normal*	< 25	39%	3.03	4.62
Overweight	≥ 25 - < 30	25%	5.36	7.98
Obese	≥ 30	35%	6.42	8.88
Non-Obese*	< 30	65%	3.94	5.35
Obese	≥ 30	35%	6.42	8.88

***Reflective of Historical CHC Trial Populations**

ITT = Intent to Treat; all results shown are based on ITT subjects ≤ 35 years of age
UB 95% CI = upper bound of the 95% confidence interval

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Favorable Safety and Tolerability Profile for Twirla in the SECURE Trial

Low rates of hormone-related adverse events, consistent with publicly available information for other low-dose combined hormonal products

Adverse Event	SECURE Trial	Prior Agile Phase 3 Trials	Ortho Evra Trials*	Quartette Trial*
Total in Safety Population	2032	1043	3322	3597
Headache	4.3%	3.7%	21.0%	12.2%
Nausea	4.1%	4.3%	16.6%	6.7%
Breast tenderness/pain/discomfort	2.0%	1.8%	22.4%	2.2%
Mood swings/changes/depression	2.7%	2.8%	6.3%	2.9%
Heavy/irregular vaginal bleeding**	1.8%	2.1%	6.4%	9.7%

**1.4% of subjects in the SECURE trial discontinued due to a bleeding-related adverse event

Serious adverse events were observed in 1.7% of the SECURE trial study population; the most common SAEs were: deep vein thrombosis, pulmonary embolism, gallbladder disease, ectopic pregnancy, depression

**Information is based on currently marketed Ortho Evra and Quartette product labels and publicly available information. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.*

SAE = Serious adverse event

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Twirla® Had a Favorable Wearability Profile in the SECURE Trial

Rates of patch-site irritation, itching, and patch detachment were low

- **Of reported patches worn, 83% had no patch site irritation and 65% had no itching**
  - If reported, most irritation and itching was mild
  - Overall, severe itching or irritation were observed in approximately 2.3% and 1.5% of patches worn
- **Of reported patches worn, the rate of detachments was low across the trial**
  - Ranged from 10% (Cycle 1) to 2% (Cycle 13)
  - Ortho Evra: Subjects with 1 patch completely detached ranged from 6% (Cycle 1) to 2% (Cycle 13)

**Information is based on currently marketed Ortho Evra and Quartette product labels and publicly available information. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.*

The NDA Resubmission is Expected to Address the Clinical CRL Questions

We expect to submit a robust data package that more clearly defines the risk/benefit profile for Twirla

✓Substantially improved study conduct

- Lower loss to follow up rate compared to previous Phase 3 trial
- Greater confidence in the reliability of the results based on improved loss to follow-up rate and focus on data quality

✓Study population reflects the broad entry criteria for the trial

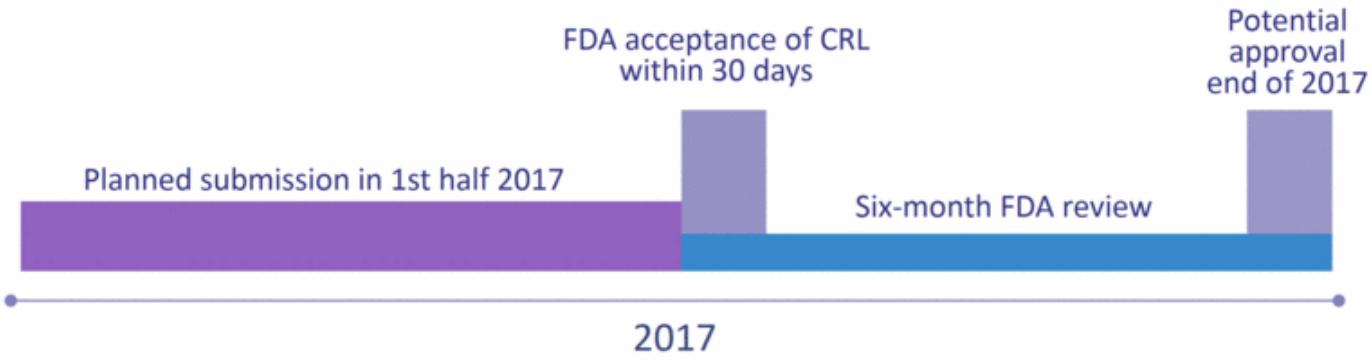
- Allowed for efficacy to be assessed across different groups
- No restrictions on BMI (unlike historical contraceptive trials)

✓Evidence of efficacy and safety

- Positive evidence of efficacy observed in a real-world study population
- Favorable safety profile; rates of adverse events consistent with publicly available information for other low-dose combined hormonal products

Potential for Approval By End of 2017

We are proud of the SECURE Trial and looking forward to sharing the data with the FDA



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APPENDIX

- FDA/Regulatory Perspective on BMI and CHC Effectiveness
  - 2007 Advisory Panel Recommendations
  - Evolution of Study Populations Around BMI/Weight
  - 2015 FDA Meta-Analysis on Obesity
- Datamonitor Study on CRL Statistics
- Contraceptive Method Effectiveness Chart

Summary of Recommendations from the 2007 FDA Advisory Committee Meeting on Contraceptive Trial Design

- Entry criteria should be more reflective of real-world prescribing regarding BMI, smoking, VTE family history
  - Subgroup analyses could be performed to assess efficacy
- Arbitrary limits for the UB of the 95% CI should be avoided in order to promote the widest range of new contraceptive products being developed and brought to market
- Substantial flexibility should be exercised in accepting given point estimates and UB of CI
- Provide all the information to the clinician and patient in an easily understandable format in labeling and let them make the final decision on which product is most appropriate
- Phase 4 trials may be used to obtain better estimates of true "actual use" effectiveness
- Product labeling should be modified to include pregnancy rates or safety data for subgroups when available

Source: 2007 FDA Advisory Committee for Reproductive Health Drugs, Summary of Recommendations
http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4274m1.pdf

Contraceptive Trials Have Historically Excluded Obese Women

Product	BMI/Weight Effect Observed	Trial Exclusions for BMI/Weight
Twirla 2017*	YES	No exclusions for BMI/weight
Quartette 2013	YES	No exclusions for BMI/weight
Agile 2013 FDA CRL		
Minastrin 2013	No	BMI > 35 kg/m^2 excluded from trials
Generess 2011	YES	
LoLoestrin Fe 2010	No	
Natazia 2010	No	BMI > 30 kg/m^2 excluded from trials
LoSeasonique 2008	No	No exclusions for BMI/weight
Lybrel 2007	No	No exclusions for BMI/weight
2007 FDA Advisory Committee for Reproductive Health Drugs		
Loestrin 24 Fe 2006	No	BMI > 35 kg/m^2 excluded from trials
Seasonique 2006	No	No exclusions for BMI/weight
Yaz 2006	No	BMI > 35 kg/m^2 excluded from trials
Seasonale 2003	No	No exclusions for BMI/weight
Ortho TriCyclen Lo 2002	No	Subjects were to be "within 35% of acceptable BMI"
Ortho Evra 2001	YES	Subjects were to be of "acceptable BMI"
Nuvaring 2001	No	BMI > 30 kg/m^2 excluded from trials
Yasmin 2001	No	Subjects were to be "within 25% of ideal body weight"

**Candidate product*

Information from publicly available information in NDA reviews and product labels

BMI = Body Mass Index
CRL = Complete Response Letter

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FDA Meta-Analysis on the Effect of Obesity on HC Effectiveness

The Division requested weight/BMI-based analyses for the Agile SECURE trial

- FDA authors called for more data in obese women from Phase 3 clinical trials after an FDA meta-analysis showed an effect of obesity on hormonal contraceptive effectiveness.
- Publication suggests 44% increased risk of pregnancy during CHC use in obese compared to non-obese women

an international reproductive health journal
Contraception

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Original research article

Effect of obesity on the effectiveness of hormonal contraceptives: an individual participant data meta-analysis

Michiyo Yamazaki[a], Kate Dwyer[b], Mahboob Sobhan[b], Daniel Davis[c], Myong-Jin Kim[a], Lisa Soule[c], Gerald Willett[c], Chongwoo Yu[a,*]

[a]Division of Clinical Pharmacology 3, Office of Clinical Pharmacology, Office of Translational Sciences (OTS), Center of Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA), Silver Spring, MD, USA
[b]Division of Biostatistics 3, Office of Biostatistics, OTS, CDER, FDA, Silver Spring, MD, USA
[c]Division of Bone, Reproductive, and Urologic Products, Office of New Drugs, CDER, FDA, Silver Spring, MD, USA

Received 20 August 2014; revised 27 July 2015; accepted 31 July 2015

Yamazaki M et al, Contraception 2015; 92: 445-52
CRL was February 2013

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Healthcare Providers Focus on Typical Use Contraceptive Effectiveness

U.S. FOOD & DRUG ADMINISTRATION
www.fda.gov/birthcontrol

BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

Most Effective ↑ ↓ Least Effective

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects* This chart does not list all of the risks and side effects for each product.
Sterilization Surgery for Women	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	Onetime procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection
IUD Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne Mood swings or depressed mood Headache
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ Bleeding between periods Headaches Nervousness Abdominal discomfort Weight gain Dizziness
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Pill" (Extended/ Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea Breast tenderness Skin irritation Stomach pain Headache
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache Nausea Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection

If approved, we expect Twirla to be included with other Tier 2 methods

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Datamonitor Analyst Study on FDA CRLs

- **CRLs were received by 42% of NDAs/BLAs**
  - 29% of NDAs receiving CRLs were withdrawn
  - 71% were resubmitted or open at time of analysis; of resubmitted NDAs with a documented FDA decision, 80 of 81 were approved
- **Most failures to gain approval were because the applicant chose not to resubmit**

DATAMONITOR Healthcare

Complete Response Letter Trends and Influence on Approval Delays

CRL = Complete Response Letter
Source: Datamonitor Analysis-Analyst Opinion; study of 356 NDAs/BLAs from Oct 2008 to Sept 2012; Jan 2013.