**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 8, 2020**
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**<br>**Princeton, New Jersey** | **08540** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code **(609) 683-1880**

(Former name or former address, if changed since last report)

---

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)).

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

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

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. ☐

**Item 2.02 Results of Operations and Financial Condition.**

As discussed below, in connection with its participation in the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California beginning on January 13th, 2020, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company had an estimated $34.5 million of cash and cash equivalents as of December 31, 2019, which includes the proceeds of approximately $19.3 million, net of expenses, from the sale of approximately 10.4 million shares of the Company's common stock, par value $0.0001 per share ("Placement Shares"), representing the full amount of shares authorized for sale by the Company in the at-the-market offering conducted pursuant to the Common Stock Sales Agreement dated November 8, 2019 (the "Sales Agreement") with H.C. Wainwright & Co., LLC. The issuance and sale of the Placement Shares by the Company under the Sales Agreement was made pursuant to a prospectus supplement to the Company's registration statement on Form S-3, originally filed with the Securities and Exchange Commission (the "SEC") on November 2, 2018, and declared effective by the SEC on November 14, 2018. The Company believes its estimated cash and cash equivalents as of December 31, 2019 will be sufficient to meet its projected operating requirements into September 2020.

Because the Company's financial statements for the year ended December 31, 2019 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2019 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

**Item 8.01. Other Events.**

Beginning on January 13, 2019, the Company will participate in the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California. The Company has updated its corporate presentation that it intends to use in connection with its presentation at the Biotech Showcase 2020 on Tuesday January 14, 2020 at 10:00 a.m. Pacific Time, at the J.P. Morgan 2020 Healthcare Conference on Thursday, January 16, 2020 at 10:30 a.m. Pacific Time, and in meetings with investors. The updates primarily involve disclosure regarding the Company's cash and cash equivalents as of December 31, 2019 as well as the Company's plans for commercialization upon the approval of AG200 (Twirla®).

A copy of the Company's corporate presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Agile Therapeutics, Inc. Presentation |

**SIGNATURES**

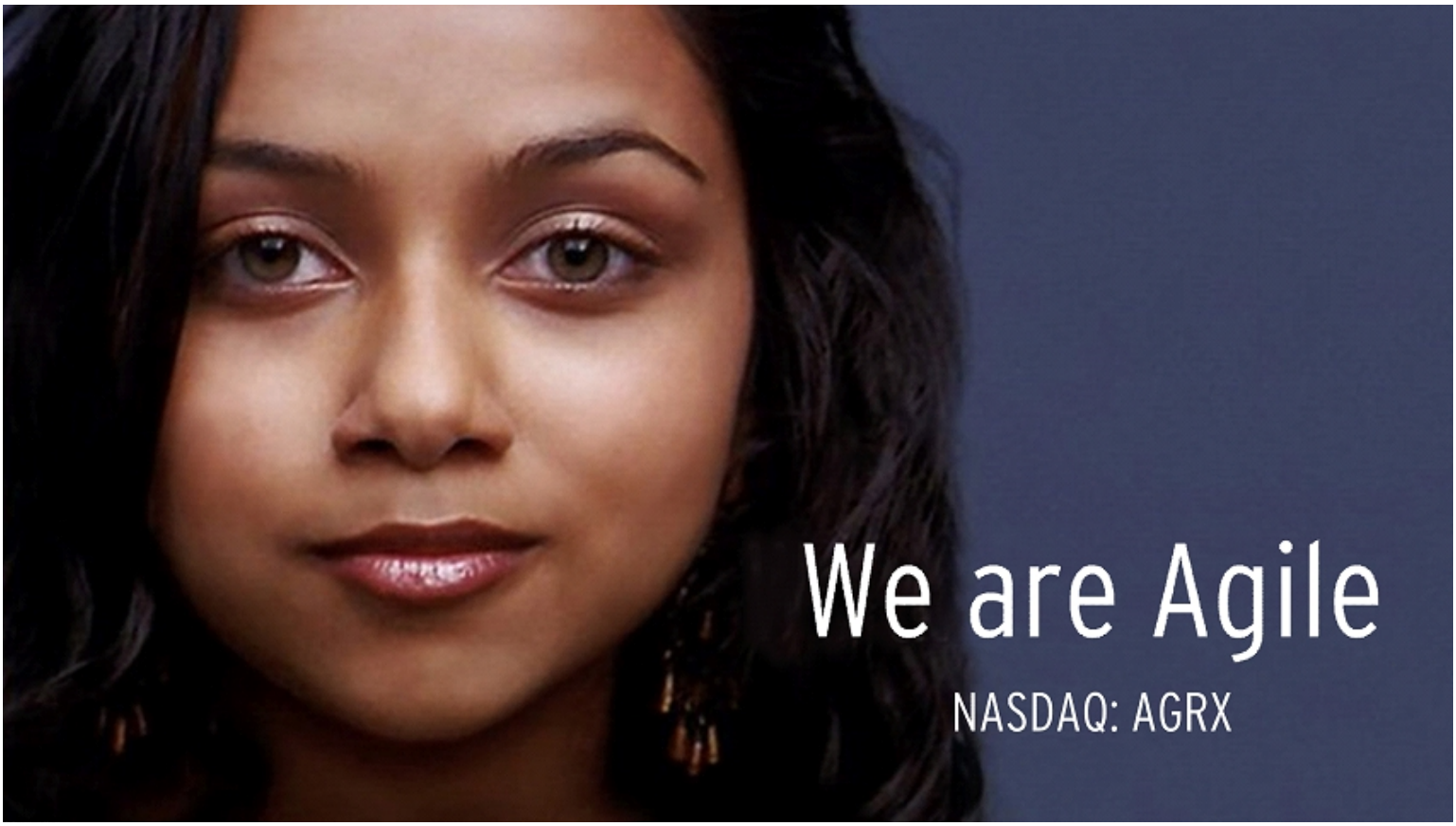
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Agile Therapeutics, Inc.**

Dated: January 8, 2020

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

**Exhibit 99.1**



# Forward Looking Statement

Certain information contained in this presentation and other matters discussed today or answers that may be given in response to questions may include "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

In particular, the Company's statements regarding projections and potential future results are examples of such forward-looking statements. The forward-looking statements are subject to important factors, risks and uncertainties, including, but not limited to, risks related to our ability to adequately respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our data do not support approval of the Twirla NDA and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the 2017 CRL, our ability to obtain and maintain regulatory approval of Twirla, the inability of our third-party manufacturer, Corium International, Inc. (Corium), to complete any work or provide any data and other information necessary to support the approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, our ability to raise capital when needed to complete the commercial launch of Twirla, and unforeseen market factors or events in our clinical, regulatory and manufacturing development plans; and other factors, including general economic conditions and regulatory developments, not within the Company's control.

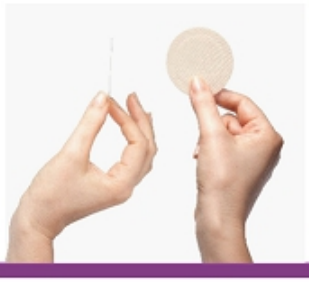
These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in "Risk Factors" in the Company's Annual Report on for 10K for the year ended December 31, 2018 and in the quarterly reports filed with the SEC.

- A champion for healthcare choices women deserve, headquartered in Princeton, NJ
- Dedicated to building a robust Women's Health Franchise
- Twirla® is our initial opportunity

Twirla™
(levonorgestrel/ethinyl estradiol)
120/30 mcg/day transdermal system

Weekly Contraceptive Patch

$3.7B
Addressable Market



# Agile's Corporate Strategy: Become a Leader in Women's Health

- Short-Term Goal - Establish Agile in the prescription contraceptive market with Twirla, our lead product candidate
- Long-Term Mission - Broaden our women's health portfolio in areas of unmet medical need

# Agile's Women's Health Mission Starts with Contraception

| | |
|---|---|
| WHY CONTRACEPTION? | Women use contraception for an average of 30 years, and nearly all women use contraception at some point[1,2] |
| | ~50% of pregnancies in U.S. women are unintended[3] |
| WHY DO WOMEN NEED MORE BIRTH CONTROL OPTIONS? | Nearly half of unintended pregnancies are due to inconsistent and/or improper use of contraception[4] |
| | Women's individual preferences for contraceptive methods vary and change across their lifetimes as their needs change[5] |
| | Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing[4] |

1-Hamilton BE, Kirmeyer SE., National Center for Health Statistics. 2017; 2-Daniels K et al, National Center for Health Statistics. 2013
3-Finer LB and Zolna MR, NEJM 2016; 4-Frost JJ and Darroch J., Perspectives on Sexual and Reproductive Health 2008
5-Mansour D, Int J Women's Health 2014

# What is Missing From Available Hormonal Birth Control Options?

*"Some women are just not good at remembering to take a pill at the same time every day…Others don't want something in their vagina while others don't want an injection."*

- Ob/Gyn

**LOWER ESTROGEN DOSE**

**The dose of estrogen in CHCs is believed to be the primary factor influencing the risk of blood clots (VTEs)[1]**

The only non-daily transdermal patch currently available delivers a high dose of estrogen[2]

**NON-DAILY OPTIONS**

**Potential to reduce burden associated with daily pills**

**49%** of contraception users prefer non-daily method[3]

**52%** are frustrated with taking the pill daily[3]

**LESS INVASIVE METHODS**

**Preferred by some women[4]**

Some women prefer to avoid injections, implants, and intrauterine devices

1-Stegeman B. H., et al, BMJ 2013; 2-Xulane Package Insert; 3-Mansour D., International Journal of Women's Health 2014; 4-Qualitative and quantitative HCP research, Kantar Health 2010; Third party research, 2017

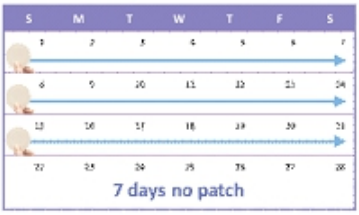
# Twirla Designed to Fill A Hormonal Birth Control Market Need


HORMONE PROFILE

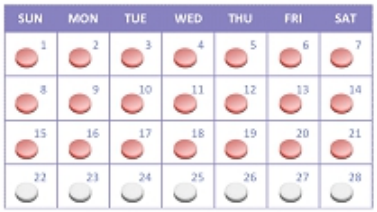
~30µg/day Ethinyl Estradiol (EE)
120µg/day Levonorgestrel (LNG)

NON-DAILY

Patch Regimen: Once-a-week




Pill Regimen: Once-a-day




LESS INVASIVE

Less invasive than some methods
(vaginal ring, IUDs, injections, implants)

*"I want to eliminate the forgetfulness... but I don't want to lose that control either."*
*– Consumer, October 2016*

Source: Qualitative consumer market research, Adelphi Research 2016

# U.S. Hormonal Contraceptive Market is a Significant Opportunity

## US Market Estimates (2018)

$5.3 Billion U.S. Contraceptive Market

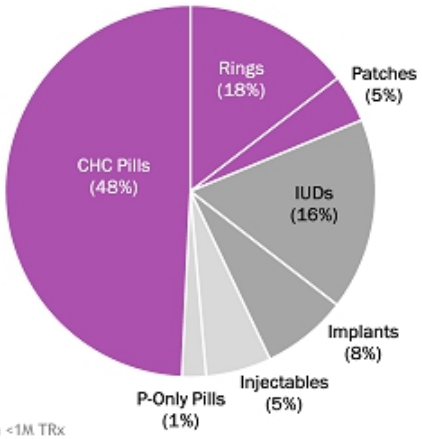
| Combined Hormonal Contraception (CHC) | Progestin-Only (P-Only) | Long Acting Reversible Contraception (LARC) |
|---|---|---|
| CHC Pill, Ring, Patch | P-only Pill, Injection | IUD, Implant |
| *$3.7 Billion* | *$300 Million* | *$1.3 Billion* |

*CHC Pills + Ring + Patch =*

***$3.7 Billion***

*Potential Addressable Market for*

Twirla




P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
Sources: IQVIA NSP through Dec 2018; ACOG FAQs

# Twirla has the Potential for Significant Market Share

## Peak TRx Share Estimate Based on Consumer & Physician Market Research and Market Analogs

| HCP Market Research (% CHC Market TRx) | | |
|---|---|---|
| Study Year | Stated Share | Calibrated for Overstatement |
| 2019 | 20% | 14% |
| 2016 | 23% | 14% |

| Consumers "Extremely Likely" to Ask for Twirla | Average of Analog Brands |
|---|---|
| 15% | 9.6% |

Twirla 6-9%

Sources: IMS NPA, 2002-2014
Qualitative and Quantitative HCP and Consumer market research, Adelphi Research 2016
Quantitative HCP market research, MarketVision Research 2019

# Twirla Pivotal Phase 3 SECURE Trial

Single-arm 13-cycle trial of ~2000 healthy subjects aged ≥ 18 at 102 U.S. clinical sites

| | | |
|---|---|---|
| **STUDY DESIGN**<br><br>Contemporary Study Design with Inclusive Patient Population | Rigorous Design | ▪ Frequent pregnancy testing<br>▪ Stringent cycle exclusion |
| | Representative of Women Seeking Hormonal Contraception | ▪ No exclusions for weight or BMI<br>▪ SECURE trial population, one of the heaviest for a CHC trial |
| **RESULTS** | Efficacy | ▪ Tight confidence interval achieved on overall results<br>▪ Pearl Index higher than previously approved products<br>▪ Effect of obesity observed |
| | Safety and Tolerability | ▪ Low rate of hormone-related adverse events<br>▪ Serious adverse events observed in 1.97% of subjects<br>▪ Bleeding profile similar to low-dose oral CHCs |
| | Wearability | ▪ Low levels of detachments, patch site irritation, and itching<br>▪ Adhesion performance improved over time with increased use<br>▪ Observed learning curve may be addressable through training |

# Recent Regulatory History


**PDUFA GOAL DATE: February 16, 2020**

# The Path To Potential Twirla Approval

| ISSUE RAISED BY FDA CRL | CLARIFICATION FROM FDA FOR NEXT STEPS |
|---|---|
| Adhesion Test Methods | ☑ New method appears reasonable and will be a review issue |
| Manufacturing Inspection Observations | ☑ Responses to initial PAI submitted. Likely subject to another PAI |
| In Vivo Adhesion | ☑ FDR completed; FDA recommended Comparative Wear Study with Xulane® |
| High Pearl Index | ☑ FDA anticipates reviewing efficacy and benefit/risk at Advisory Committee |
| REGULATORY MILESTONES ACHIEVED TO DATE | ☑ Achieved Primary Endpoint in Comparative Wear Study & Demonstrate Non-Inferior Adhesion to Xulane®<br>☑ Completed NDA Submission to FDA<br>☑ Completed PAI at Corium<br>☑ Favorable FDA Advisory Committee on Efficacy and Benefit/Risk |

**PDUFA GOAL DATE: February 16, 2020**

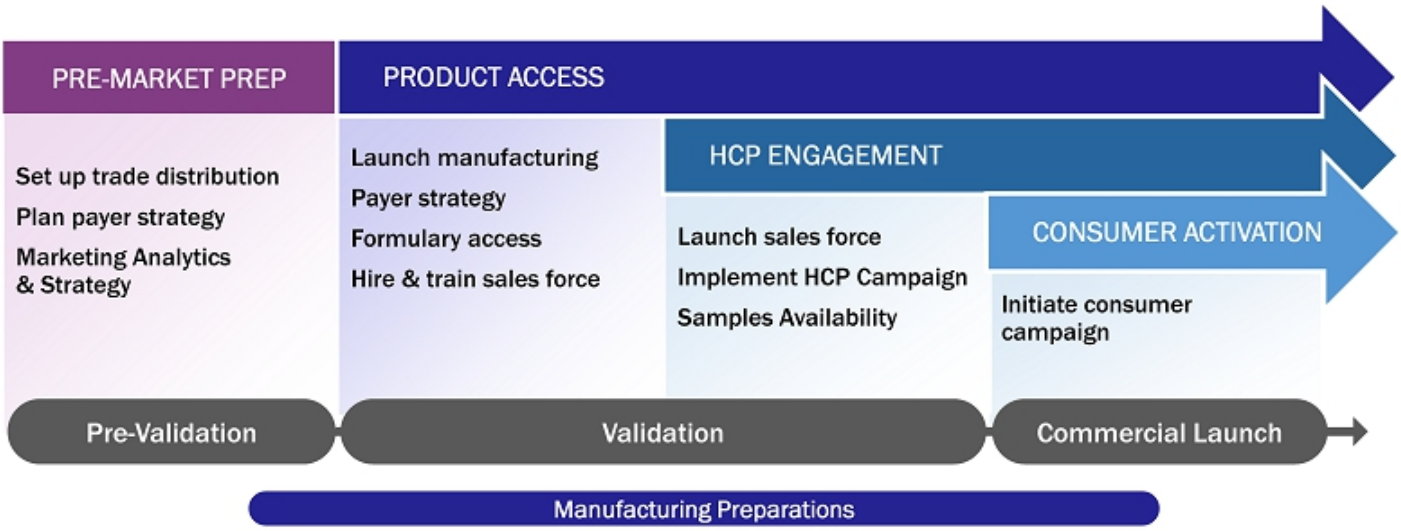
# Agile Has Activated Partners to Prepare for Twirla Commercial Readiness

| MANUFACTURING | MARKET ACCESS | LAUNCH NETWORK | SALES FORCE |
|---|---|---|---|
| ▪ Corium is an experienced contract patch manufacturer<br>▪ Qualification of commercial scale equipment in final stages<br>▪ Plan for completion of validation after approval | ▪ Agile knows its market<br>▪ Top 8 payers expected to cover majority of commercial lives[1]<br>▪ Strategic contracting to place Twirla in competitive reimbursement position | ▪ Relationships with experienced vendors to facilitate commercial launch<br>▪ Vendors have expertise in marketing, PR, market access, and supply chain | ▪ Small, targeted sales force (70-100 reps) to launch<br>▪ Phased hiring linked to formulary acceptance<br>▪ Focus on high-prescribing Ob/Gyns and women's health NP/PAs |

Twirla™

Sources 1-Berchick E, Hood E, Barnett J,. Health Insurance Coverage in the United State 2017
Haefner, M. America's largest health insurers in 2018

# Phased Approach to Commercial Strategy

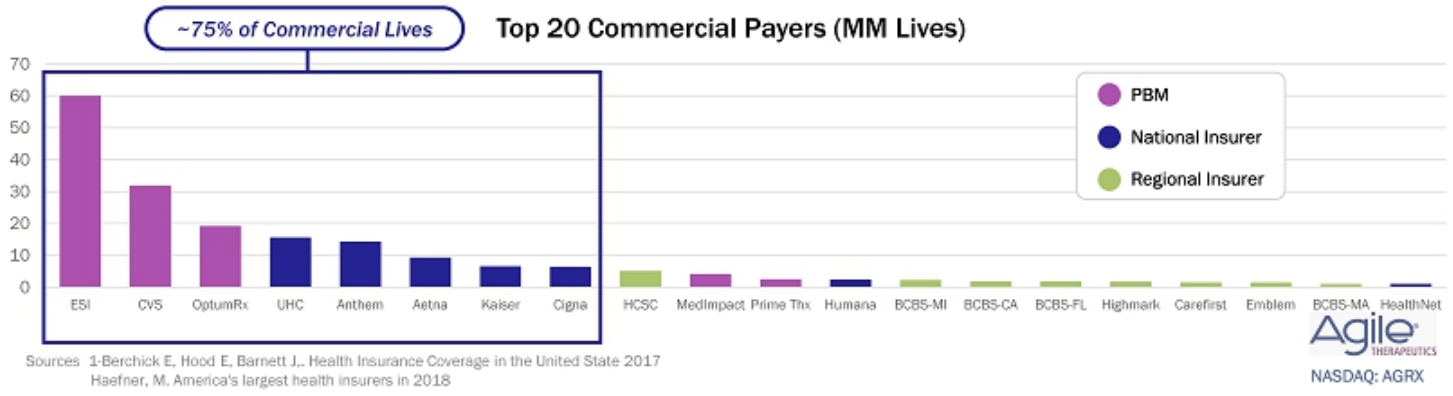


# Managed Care Strategy: Minimize Access Barriers

**Twirla® Managed Care Strategy**

- Affordable Care Act
- State Mandates
- Pricing Strategy
- Patch Replacement Program

→ Strategy Will Inform Sales Force Rollout Plan




Sources 1-Berchick E, Hood E, Barnett J,. Health Insurance Coverage in the United State 2017
Haefner, M. America's largest health insurers in 2018

NASDAQ: AGRX

# AGRX Financial Overview

Balance Sheet

**$34.5 Million cash on hand at December 31, 2019 (Unaudited)**

- The Company believes its estimated cash and cash equivalents as of December 31, 2019 will be sufficient to meet its projected operating requirements into September 2020

Capital

**$100.0 Million Universal Shelf Registration Statement on Form S-3**

- In 2019, $42.3 million in total net proceeds raised through a private placement, public offering and our "At-the-Market" program offerings.
- 69.8 Million common shares outstanding at December 31, 2019.

# Summary of Agile Therapeutics Opportunity

| | |
|---|---|
| WHAT IS OUR INITIAL FOCUS? | ▪ A non-daily, less invasive contraceptive option – **Twirla®**<br>▪ Expect to launch into $3.7B addressable market<br>▪ 6-9% peak TRx market share estimate |
| WHY ARE WE WELL-POSITIONED TO EXECUTE OUR PLAN? | ▪ Experienced management team with the ability to plan and execute<br>▪ Activated partners to prepare for commercial readiness<br>▪ Building out internal capabilities |
| WHAT DID WE SUCCESSFULLY COMPLETE IN 2019? | 2019 MILESTONE — COMPLETION DATE<br>Conduct Comparative Wear Study & Meet Primary Endpoint — Completed Feb 2019<br>Pre-Approval (PAI) Inspection at Manufacturer — Completed Oct 2019<br>Advisory Committee on Twirla — Completed Oct 2019 |
| WHAT'S NEXT FOR 2020? | 2020 MILESTONE — PROJECTED DATE<br>Twirla PDUFA Goal Date — February 16, 2020<br>Initial Shipment of Product — 2H 2020 |

# Appendix

# Evidence of Efficacy in a Representative 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 |

Prespecified analyses showed an effect of obesity:

| 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

Pearl Index = $\frac{\text{\# On-treatment pregnancies}}{\text{\# Cycles}} \times 1300$

Pearl Index with no contraception[1]: ~190

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
Source: [1]Personal correspondence with Dr. James Trussell

# Life Table Efficacy is Another Clinical Measure

- Failure rate (Life table analysis) is an important pre-specified, supplemental efficacy endpoint in contraceptive trials
- Failure rate was 4.2% at Cycle 13, inclusive of all subjects regardless of BMI

95.8% of SECURE trial subjects did not have a pregnancy during the trial

| Cycle | % of Subjects With a Pregnancy | UB of 95% CI |
|---|---|---|
| 1 | 0.2 | 0.51 |
| 2 | 0.6 | 1.15 |
| 3 | 1.0 | 1.64 |
| 4 | 1.6 | 2.40 |
| 5 | 2.0 | 2.84 |
| 6 | 2.6 | 3.58 |
| 7 | 2.8 | 3.77 |
| 8 | 3.2 | 4.28 |
| 9 | 3.4 | 4.50 |
| 10 | 3.5 | 4.61 |
| 11 | 3.7 | 4.85 |
| 12 | 3.9 | 5.10 |
| 13 | 4.2 | 5.48 |

UB 95% CI = upper bound of the 95% confidence interval

# Safety and Tolerability Profile in the Phase 3 Trials

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

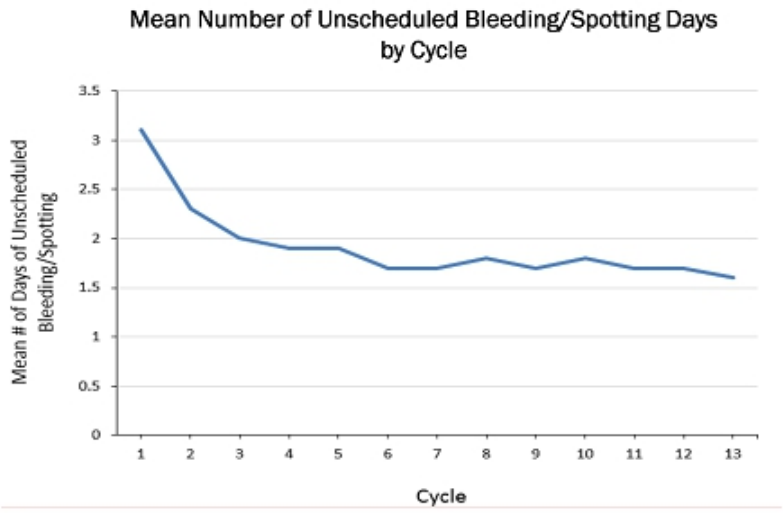
| Adverse Event* | SECURE Trial | Prior Agile Phase 3 Trials | Ortho Evra Trials* | Quartette Trial* |
|---|---|---|---|---|
| Total in Safety Population | 2031 | 1043 | 3322 | 3597 |
| Headache | 4.5% | 3.7% | 21.0% | 12.2% |
| Nausea | 4.1% | 4.3% | 16.6% | 6.7% |
| Breast tenderness/pain/discomfort | 2.0% | 1.8% | 22.4% | 2.2% |
| Mood swings/changes/depression | 2.7% | 2.8% | 6.3% | 2.9% |
| Heavy/irregular vaginal bleeding | 2.6% | 2.1% | 6.4% | 9.7% |

- Overall serious adverse events (SAEs) were observed in 1.97% of the SECURE trial study population; generally in line with those observed in other low-dose combined hormonal products* (rate in Quartette trial = 1.6%); 0.7% of subjects had SAEs that were considered potentially study drug related, including deep vein thrombosis (DVT), pulmonary embolism (PE), gallbladder disease, ectopic pregnancy, and depression
- In the combined safety database for Agile Phase 3 trials (n >3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI >30kg/m2)

*Information is based on currently marketed product labels and publicly available information; adverse event (AE) terms utilized in table (except nausea) represent composites of relevant specific AE preferred terms. Different terminology may be used in product labels and reports. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.

# Bleeding Profile Similar to Oral Low-Dose CHCs

- Bleeding-related side effects are among the top reasons women discontinue hormonal contraception[1]
- Monthly withdrawal bleeding duration (mean 3-3.7 days) in SECURE trial subjects was generally consistent with approved low-dose CHCs
- Breakthrough bleeding also generally consistent with approved low-dose CHCs[2] and decreased during the 13 cycles of the study
- 2.2% of SECURE trial subjects discontinued due to a bleeding-related adverse event (Quartette: 5%; Natazia: 2.3%; Ortho Evra 1.1%)

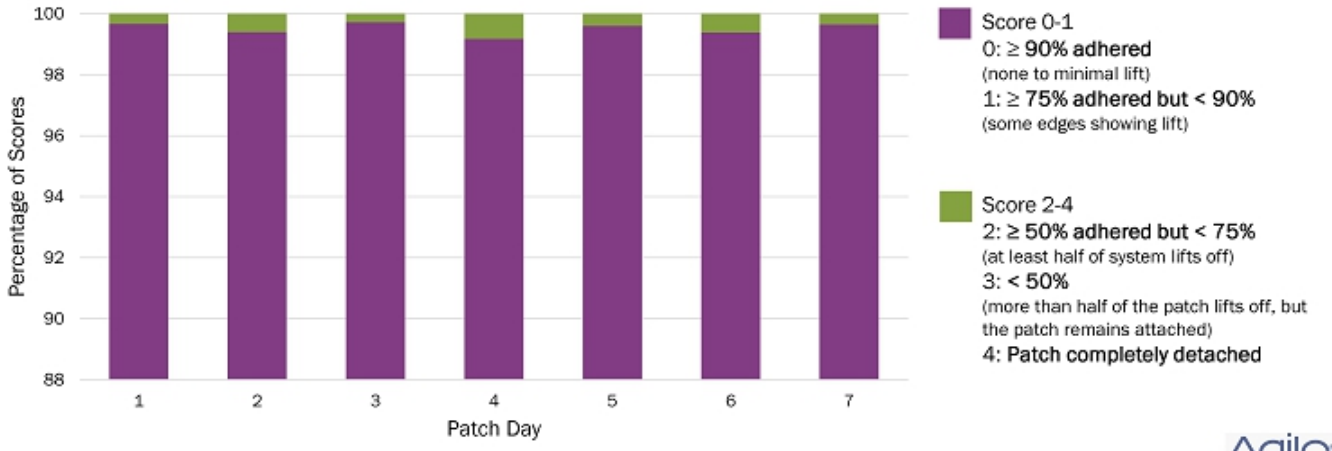



Analysis of subjects in the Safety Population of SECURE trial
1-Moreau C, et al. *Contraception* 2007 ; 2-publicly available product labels

# Adhesion Profile in the SECURE Trial

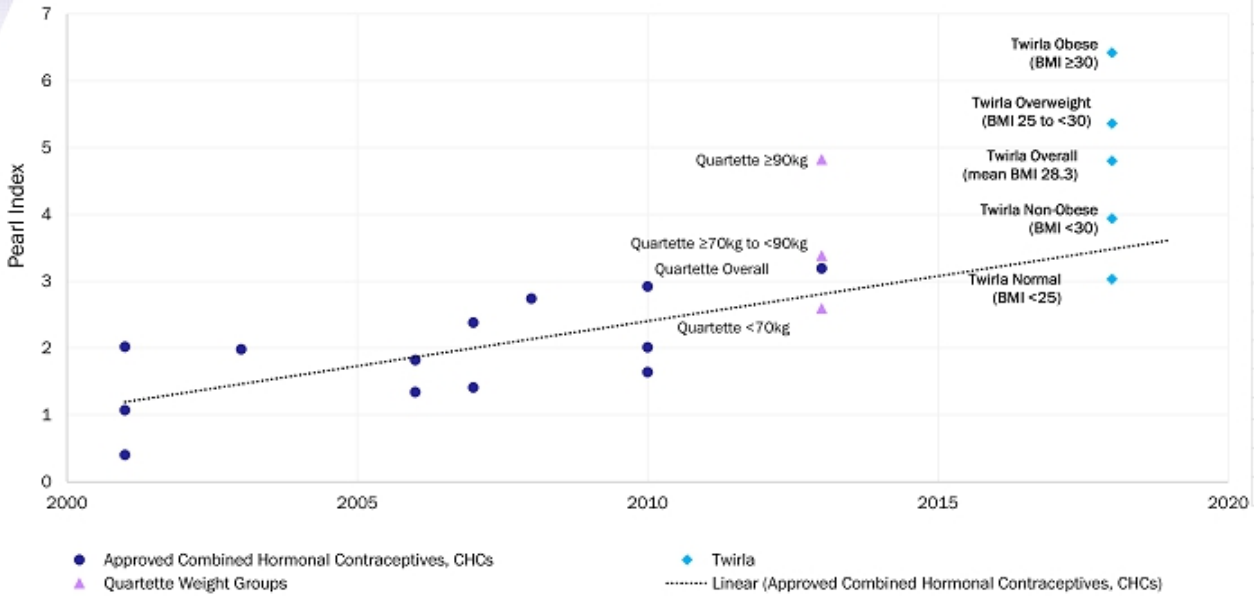
- 99.2 - 99.7% of patch adhesion scores ranged from no lifting of the patch (score = 0) to slight lifting at the edges (score = 1)

5-point scale provided by the FDA



# Observable Trend in Pearl Indices for Approved Combined Hormonal Contraceptives (CHCs)

**Historical Pearl Indices for CHCs Approved Since 2000 and the Pearl Indices Observed in the SECURE Trial**




| Product (Year Approved) | Pearl Index |
|---|---|
| Ortho Evra (2001) | 1.07 |
| Nuvaring (2001) | 2.02 |
| Yasmin (2001) | 0.4 |
| Seasonale (2003) | 1.98 |
| Loestrin 24 FE (2006) | 1.82 |
| Seasonique (2006) | 1.34 |
| Yaz (2007) | 1.41 |
| Lybrel (2007) | 2.38 |
| LoSeasonique (2008) | 2.74 |
| Natazia (2010) | 1.64 |
| LoLoestrin (2010) | 2.92 |
| Generess (2010) | 2.01 |
| Quartette (2013) | 3.19 |
| | |
| Quartette ≥90kg | 4.82 |
| Quartette ≥70 to <90kg | 3.38 |
| Quartette <70kg | 2.59 |

Approved Combined Hormonal Contraceptives, CHCs
Quartette Weight Groups
Twirla
Linear (Approved Combined Hormonal Contraceptives, CHCs)

Sources: Trussell, et al., *The Creeping Pearl* (2013), currently marketed product labels, and publicly available information

# Twirla Demonstrates Non-Inferior Adhesion to Xulane in Comparative Wear Study

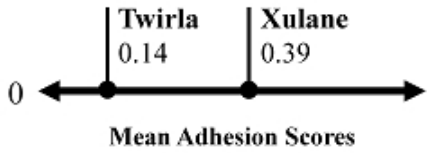
**STUDY DESIGN**

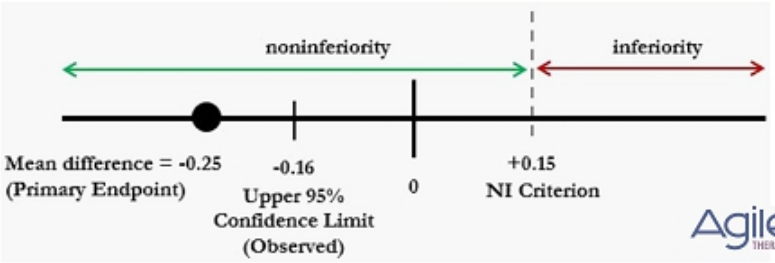
- Subjects randomized to wear either Twirla or Xulane for Week 1, then switched to the other patch for Week 2
- Investigators assigned a daily patch adhesion score using a 5-point scale from 0 (essentially no patch lift off skin) to 4 (complete patch detachment)

Patch Adhesion Score Range: 0 (no lift) ⟷ 4 (detachment)

- **Primary endpoint** - mean difference in adhesion scores between Twirla and Xulane
- **Non-Inferiority (NI) criterion** – mean difference between upper 95% confidence limits must be less than +0.15

**RESULTS: NON-INFERIORITY CRITERION MET ☑**




Note: Graph is for illustrative purposes only and is not to scale

# Comparative Wear Study

Comparing the adhesion of Twirla to that of Xulane, the generic version of Ortho Evra

| | |
|---|---|
| **Study Design** | ▪ Study design is consistent with the 2018 ANDA Guidance document entitled *Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs*<br>▪ Randomized, open-label, crossover adhesion study<br>▪ Healthy women aged 18-35 years with Body Mass Index (BMI) <35 kg/m$^2$<br>▪ 77 subjects were included in the Per Protocol population used in the primary analysis<br>▪ Subjects were randomized to wear either Twirla or Xulane for the first week then switched to the patch not initially worn for the second week<br>▪ Investigators assessed patch adhesion for each day of wear and assigned the patch a daily score of 0 (essentially no patch lift off skin) to 4 (complete patch detachment) |

**POSITIVE TOPLINE RESULTS**

- The mean score for Twirla (0.14) was numerically better than the mean score for Xulane (0.39), producing a negative mean difference (-0.25)
- No complete detachments of Twirla or Xulane occurred during the trial
- The upper bound of the 95% confidence limit for the mean difference is -0.16, thus Twirla met the non-inferiority criterion of +0.15

# Contraceptive Use by U.S. Women

CONTRACEPTIVE METHOD CHOICE

**Most effective method used in the past month by U.S. women, 2014**

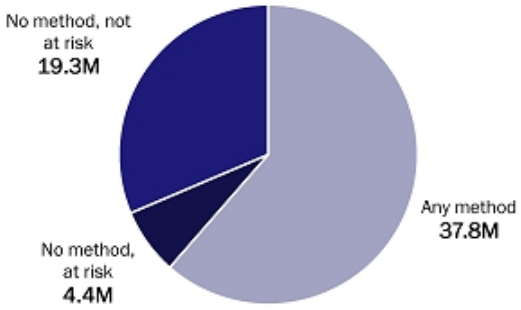
| METHOD | No. of women | % of women aged 15–44 | % of women at risk of unintended pregnancy | % of contraceptive users |
|---|---|---|---|---|
| Pill | 9,572,477 | 15.6 | 22.7 | 25.3 |
| Tubal (female) sterilization | 8,225,149 | 13.4 | 19.5 | 21.8 |
| Male condom | 5,496,905 | 8.9 | 13.0 | 14.6 |
| IUD | 4,452,344 | 7.2 | 10.6 | 11.8 |
| Vasectomy (male sterilization) | 2,441,043 | 4.0 | 5.8 | 6.5 |
| Withdrawal | 3,042,724 | 5.0 | 7.2 | 8.1 |
| Injectable | 1,481,902 | 2.4 | 3.5 | 3.9 |
| Vaginal ring | 905,896 | 1.5 | 2.1 | 2.4 |
| Fertility awareness-based methods | 832,216 | 1.3 | 2.0 | 2.2 |
| Implant | 965,539 | 1.6 | 2.3 | 2.6 |
| Patch | 69,106 | 0.1 | 0.2 | 0.2 |
| Emergency contraception | 69,967 | 0.1 | 0.2 | 0.2 |
| Other methods* | 234,959 | 0.4 | 0.6 | 0.6 |
| No method, at risk of unintended pregnancy | 4,408,474 | 7.2 | 10.5 | na |
| No method, not at risk | 19,302,067 | 31.4 | na | na |
| Total | 61,491,766 | 100.0 | 100.0 | 100.0 |

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers to women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontraceptively sterile. na=not applicable.

*In 2014

Source: Fact Sheet - Contraceptive Use In the United States, Guttmacher Institute, July 2018

Contraceptive Method Choice
(Number of U.S. Women*)




| Number of U.S. women using a CHC method* (pill, ring, patch) | 10,547,479 |
|---|---|

# Average Price Per Cycle for Branded CHCs ($WAC)