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

February 14, 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 **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 filing 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(s)	Name of each 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. ☐

Item7.01 Regulation FD Disclosure

On February 14, 2020, Agile Therapeutics, Inc. (the "Company") issued a press release announcing that on February 14, 2020, the U.S. Food and Drug Administration ("FDA") approved Twirla as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate. The Company is furnishing herewith a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in this Item 7.01 (including Exhibit 99.1 attached 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 the Securities Act, except as shall be expressly set forth by specific reference in such a filing.

Item9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated February 14, 2020.

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: February 18, 2020

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

Exhibit 99.1

NEWS RELEASE

FOR IMMEDIATE RELEASE

FDA Approves Agile Therapeutics, Inc.'s Twirla® (levonorgestrel and ethinyl estradiol) Transdermal System– A New Weekly Contraceptive Patch Delivering a 30 mcg Daily Dose of Estrogen and 120 mcg Daily Dose of Progestin

Twirla® is a new non-daily, non-invasive contraceptive approved in the U.S.

PRINCETON, N.J., February 14, 2020– Agile Therapeutics, Inc., (Nasdaq: AGRX) (Agile or the Company), a forward-thinking women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has approved Twirla® (levonorgestrel and ethinyl estradiol) transdermal system.

INDICATION AND USAGE

TWIRLA is indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate.

Limitations of Use

Consider TWIRLA's reduced effectiveness in women with a BMI $\geq$ 25 to < 30 kg/m^2 before prescribing. TWIRLA is contraindicated in women with a BMI $\geq$ 30 kg/m^2.

Please see Important Safety Information for TWIRLA, including BOXED WARNING on Cigarette Smoking and Serious Cardiovascular Events and Contraindication in Women with a BMI $\geq$ 30 kg/m^2, below in "About Twirla."

"Twirla is an important addition to available hormonal contraceptive methods, allowing prescribers to now offer appropriate U.S. women a weekly transdermal option that delivers estrogen levels in line with labeled doses of many commonly prescribed oral contraceptives," said Dr. David Portman, a primary investigator on the SECURE clinical trial. "I'm pleased that Agile conducted a comprehensive study in a diverse population providing important data to prescribers and to women seeking contraception. It is vital to expand the full range of contraceptive methods and inform the choices that fit an individual's family planning needs and lifestyle. I am excited healthcare providers can now include Twirla among available contraception options."

Twirla is designed for weekly application to deliver a 30 mcg daily dose of ethinyl estradiol, a type of estrogen, along with a 120 mcg daily dose of levonorgestrel, a well-known progestin with a long history in the category. The newly approved patch can be worn on the abdomen, buttock, or upper torso (excluding the breasts).

“The FDA’s approval of Twirla will enable us to deliver on our short-term goal of establishing Agile in the contraceptive prescription market and working towards our longer-term mission to broaden our women’s health portfolio, including in areas of unmet need. We are grateful to the clinical trial patients, researchers, healthcare providers, and advocates, whose contributions helped us secure the approval of a new transdermal contraceptive option that may serve the contraceptive needs and preferences of many women,” said Al Altomari, chairman and chief executive officer, Agile Therapeutics. "We are proud to offer this new option and look forward to bringing Twirla to women and their healthcare providers.”

As part of Twirla’s approval, the FDA is requiring Agile to conduct a long-term prospective, observational post-marketing study comparing the risks for venous thromboembolism (VTE) and arterial thromboembolism (ATE) in new users of Twirla to new users of other combined hormonal contraceptives (CHC). The FDA’s requirement for Twirla is similar to another post-marketing study requirement for a recently approved CHC. The final study report for the Twirla study is scheduled to be submitted to the FDA in November 2032, with interim safety data reporting to the FDA due in November 2026. Agile has also agreed to a post-marketing commitment (PMC) study to assess the residual drug content and strength of Twirla in a minimum of 25 women, which will analyze the Twirla ethinyl estradiol and levonorgestrel content after the prescribed wear and will monitor adhesion. The PMC is similar to residual drug studies requested of patch developers in the FDA’s November 2019 draft guidance entitled *Transdermal and Topical Delivery Systems – Product Development and Quality Considerations.* The Company plans to begin designing the post-approval studies and evaluating related costs during the first half of 2020.

With the approval of Twirla, Agile will accelerate its commercial activities. In the first quarter of 2020, Agile plans to initiate work with managed care and patient payors to gain market access for Twirla. Beginning in the second quarter of 2020, the Company plans to hire and train an initial sales team. In parallel with these activities, Agile plans to complete the validation of its commercial manufacturing process and expects to ship initial product to wholesalers in the fourth quarter of 2020. The Company believes that the potential new CHC users who have a BMI <30 kg/m^2 represent a significant population of women. Based on the Company’s market research, analysis of the current and expected future U.S. contraceptive market, and review of other product launches in the category, the Company estimates that Twirla can potentially achieve a peak market share of 5-8%. As the Company prepares for the commercialization of Twirla, it will continue to analyze the contraceptive market and update its market research as it evaluates the commercial opportunity for Twirla.

About Twirla

IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS and CONTRAINDICATED IN WOMEN WITH A BMI ≥ 30 KG/M^2

Cigarette Smoking and Serious Cardiovascular Events
Cigarette smoking increases the risk of serious cardiovascular events from combined hormonal contraceptive (CHC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs, including TWIRLA, are contraindicated in women who are over 35 years of age and smoke.

Contraindicated in Women with a BMI ≥ 30 kg/m^2
TWIRLA is contraindicated in women with a BMI ≥ 30 kg/m^2. Compared to women with a lower BMI, women with a BMI ≥ 30 kg/m^2 had reduced effectiveness and may have a higher risk for venous thromboembolism events (VTEs).

CONTRAINDICATIONS

TWIRLA is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic disease, including women with a BMI ≥ 30 kg/m^2; have headaches with focal neurological symptoms, migraine with aura, women over 35 years of age with any migraine headache; liver tumors, acute viral hepatitis, or severe (decompensated) cirrhosis, or liver disease; undiagnosed abnormal uterine bleeding; pregnancy; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; hypersensitivity to any components of TWIRLA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- **Thromboembolic Disorders and Other Vascular Conditions-**
  Women are at increased risk for a venous thromboembolic event (VTE) when using TWIRLA
  - Stop TWIRLA if an arterial or venous thrombotic/thromboembolic event occurs
  - Stop TWIRLA if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately
  - Discontinue TWIRLA during prolonged immobilization and, if feasible, stop TWIRLA at least 4 weeks before and through 2 weeks after major surgery
  - Start TWIRLA no earlier than four weeks after delivery in women who are not breast-feeding
  - Before starting TWIRLA, evaluate any past medical history or family history of thromboembolism or thromboembolic disorders and consider whether history suggests inherited or acquired hypercoagulopathy

  Arterial Events- CHCs increase the risk of cardiovascular events and cerebrovascular events, such as myocardial infarction and stroke, particularly among older women (> 35 years of age), smokers, and women with hypertension, dyslipidemia, diabetes, or obesity.

- **Liver Disease**- Discontinue TWIRLA if jaundice develops

- **Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment-**
  Discontinue TWIRLA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. TWIRLA can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

- **Hypertension**- Monitor blood pressure at routine visits and stop TWIRLA if blood pressure rises significantly. An increase in blood pressure has been reported in women using CHCs, and this increase is more likely in older women with extended duration of use.

- **Gallbladder Disease-** Studies suggest CHCs increase risk of developing gallbladder disease and may also worsen existing gallbladder disease.

- **Adverse Carbohydrate and Lipid Metabolic Effects-**
  - TWIRLA may decrease glucose tolerance. Carefully monitor prediabetic and diabetic women who are using TWIRLA.
  - Consider alternative contraception for women with uncontrolled dyslipidemia. TWIRLA may cause adverse lipid changes. Women with hypertriglyceridemia, or a family history thereof, may have an increase in serum triglyceride concentrations when using TWIRLA, which may increase the risk of pancreatitis.

- **Headache**- If a woman using TWIRLA develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue TWIRLA if indicated. Consider discontinuation of TWIRLA if there is any increased frequency or severity of migraines during CHC use (which may be prodromal of a cerebrovascular event).

- **Bleeding Irregularities and Amenorrhea**- Women using TWIRLA may experience unscheduled bleeding, especially during the first three months of use, or experience absence of scheduled bleeding. If bleeding persists or occurs after previously regular cycles on TWIRLA, or if scheduled bleeding does not occur, evaluate for causes such as pregnancy or, in the case of unscheduled bleeding, malignancy.

- **Other Warnings and Precautions-** Other warnings and precautions include, depression, cervical cancer, increased serum concentrations of binding globulins, hereditary angioedema, and chloasma.

ADVERSE REACTIONS

The following serious adverse reactions occurred in <1% of women who received TWIRLA: cholelithiasis, cholecystitis, major depression, suicidal ideation, appendicitis, ectopic pregnancy, pneumonia, and gastroenteritis. A total of four VTEs in TWIRLA-treated patients were identified in the Phase 3 clinical trial. The most common adverse reactions (≥2%) in clinical trials for TWIRLA are application site disorders, nausea, headache, dysmenorrhea, and increased weight.

Patients should be counseled that TWIRLA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of TWIRLA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with TWIRLA.

INDICATIONS AND USAGE

TWIRLA is indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m^2 for whom a combined hormonal contraceptive is appropriate.

Limitations of Use:

Consider TWIRLA's reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m^2 before prescribing TWIRLA. TWIRLA is contraindicated in women with a BMI ≥ 30 kg/m^2.

This is not a comprehensive list of safety information related to TWIRLA.

Please See Full Prescribing Information, including BOXED WARNING.

To report **SUSPECTED ADVERSE REACTIONS**, call 1-855-888-2467 or report via the FDA MedWatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

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. Twirla and 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. Twirla® and our pipeline products are based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

Follow Agile on Linked In and Twitter: @AgileTher.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements", within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our regulatory submissions for Twirla. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "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, including statements regarding the market availability of Twirla. 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. These forward-looking statements are subject to risks and uncertainties including risks related to our ability maintain regulatory approval of Twirla, our ability along with our third-party manufacturer, 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 ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. 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, Inc.

Contact: Investor Relations -- 609-683-1880