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

December 7, 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. ☐

Item 8.01. Other Events.

On December 7, 2020, Agile Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. commercial launch of Twirla® (levonorgestrel/ethinyl estradiol) transdermal system, a new non-daily, non-invasive contraceptive patch.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated December 7, 2020

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: December 7, 2020

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

Exhibit 99.1

Agile Therapeutics Announces Nationwide Commercial Launch and Availability of Twirla® (levonorgestrel and ethinyl estradiol) Transdermal System, a New Non-Daily, Non-Invasive Contraceptive Patch

Once-Weekly Twirla is the first and only contraceptive patch that combines levonorgestrel and ethinyl estradiol (EE)

PRINCETON, N.J., December 7, 2020 – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced the U.S. commercial launch of Twirla® (levonorgestrel and ethinyl estradiol) transdermal system, a new non-daily, non-invasive contraceptive patch. Twirla is now available in the United States by prescription for women of reproductive potential with a body mass index (BMI) <30 kg/m^2 for whom a combined hormonal contraceptive is appropriate to prevent pregnancy. Twirla is less effective in women with a BMI ≥ 25 kg/m^2 to < 30 kg/m^2 and should not be used in women with a BMI ≥ 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 ≥ 30 kg/m^2, below in "About Twirla." In a clinical trial, the most common adverse events were skin reactions at the patch site, nausea, headache, menstrual cramps, and weight gain.

"We are thrilled to launch our first commercial product, Twirla, an effective, modern contraceptive option, for women and their healthcare providers," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Family planning experts believe the most successful contraception for a woman is one of her choosing that fits her lifestyle, and we believe Twirla will be a valuable addition to the category's available options. We are committed to seeking ways to make Twirla affordable and accessible for women."

Twirla is worn weekly and delivers a 30 mcg daily dose of ethinyl estradiol, the lowest exposure of estrogen in a transdermal contraceptive option[1], along with a 120 mcg daily dose of levonorgestrel, a well-known progestin with a long history of use in the category. Twirla is designed to be worn on the abdomen, buttock, or upper torso (excluding the breasts), using Skinfusion® technology. At less than 1mm thin, Twirla is made up of five distinct layers for focused drug delivery and to help maintain adhesion.

"Nearly all women use contraception at some point in their lives, but when it comes to preventing unplanned pregnancies, 90% of failures are attributed to inconsistent and/or improper use," said Donnica Moore, MD, women's health expert and advocate, President, Sapphire Women's Health Group and consultant to Agile Therapeutics. "Today, women need a birth control product that is not only safe and reliable, but also that fits seamlessly into an active lifestyle. The soft and flexible design of Twirla contours to a woman's body, requires no invasive procedures, and reduces the burden of daily administration. I am excited that healthcare providers can now offer a new solution that can fill a gap in hormonal contraceptive care."

"The approach that we have taken in the development and launch of Twirla is representative of Agile's ongoing dedication to addressing the unmet needs of today's women," said Paul Korner, MD, MBA, Chief Medical Officer of Agile. "Not only did we design our Phase 3 trial to closely represent the U.S. demographics of women, but we also worked with women over the last four years to better understand their evolving needs to ensure our patient programs holistically support women who use Twirla."

To provide women with additional personalized resources, Agile has introduced an insight-driven experience, called *The Loop* (http://www.Twirla.com/TheLoop). *The Loop* will serve as an online destination where women can get meaningful resources as they navigate their birth control journeys. Twirla patients can access the Twirla patch replacement program, chat with qualified nurse-educators about patch use, and read specially curated content designed to inspire Twirla women beyond the brand. *The Loop* is designed to create a sense of community by bringing together and celebrating women who embody the Twirla spirit of courage and confidence.

Women who would like to learn more about Twirla as a potential contraceptive option should speak to their doctor or a healthcare provider. For more information on Twirla, consumers and healthcare providers can visit www.Twirla.com.

[1]Xulane [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; 2020.

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/paraparesis/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 women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our initial product, Twirla®, (levonorgestrel and ethinyl estradiol) transdermal system is a non-daily prescription contraceptive. Twirla is 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.

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. 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 market availability and uptake of Twirla, and the expected structure of our commercialization plan for Twirla among others. 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 to maintain regulatory approval of Twirla, the ability of our third party manufacturer, Corium, to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize and obtain market access for 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, the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely upon as well as on our potential customer base, 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.

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