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

November 14, 2019
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))

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 x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 8.01. Other Events

On November 14, 2019, Agile Therapeutics, Inc. ("Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has extended the Prescription Drug User Fee Act ("PDUFA") goal date for its review of the New Drug Application ("NDA") of Twirla® (levonorgestrel/ethinyl estradiol) transdermal system, an investigational combined hormonal contraceptive patch, from November 16, 2019 to February 16, 2020. A copy of the Company's press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated November 14, 2019.

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: November 14, 2019

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

NEWS RELEASE

FOR IMMEDIATE RELEASE

Agile Therapeutics Announces FDA Extension of Twirla® NDA Review Period

PRINCETON, NJ, **November 14, 2019** Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) of Twirla® (levonorgestrel/ethinyl estradiol) transdermal system, an investigational combined hormonal contraceptive patch, from November 16, 2019 to February 16, 2020.

On October 30, 2019, the FDA's Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) met to discuss the benefits and risks of Twirla and voted 14 to 1, with one abstention, that the benefits of Twirla (AG200-15) in the prevention of pregnancy outweigh the risks to support approval. Although the FDA considers the non-binding recommendation of this panel, the final decision regarding the approval of the product is made by the FDA alone.

After the BRUDAC meeting, at the FDA's request, Agile submitted additional information to the NDA concerning topics discussed at the BRUDAC meeting. FDA determined that these submissions constitute a major amendment and will take additional time to review. According to FDA's current PDUFA Performance Goals, an FDA decision to extend the review period typically is limited to situations where review of the new information could address an outstanding issue(s) and potentially lead to approval in the current review cycle.

"We look forward to continuing our discussions with the FDA," said Al Altomari, Chairman and Chief Executive Officer of Agile. "We remain committed to bringing this important contraceptive option to women."

About Twirla® (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational, once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients ethinyl estradiol (EE), a type of estrogen, and levonorgestrel (LNG), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. after resubmitting a New Drug Application (NDA) for Twirla on May 16, 2019.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla® (levonorgestrel/ethinyl estradiol transdermal system), also known as AG200-15, is an investigational, 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, 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 approvability and subsequent availability of Twirla, the interpretation of data that supports the approval of Twirla, and the timing of the FDA's review of the Twirla NDA. 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 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, 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

Contact: Investor Relations — 609-683-1880