AGILE THERAPEUTICS INC
Form 8-K
January 10, 2019

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 9, 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 **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:

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))

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 January 10, 2019, Agile Therapeutics, Inc. (the Company) issued a press release announcing that on January 9, 2019, it received final meeting minutes from its December 11, 2018 meeting with the U.S. Food and Drug Administration s (FDA) Division of Bone, Reproductive, and Urologic Products (DBRUP). The Company met with DBRUP to discuss the design of a comparative wear study between Twirla® and Xulane® (the comparative wear study) as suggested by FDA s Office of New Drugs (OND) in its decision on the Company s previously announced formal dispute resolution request. In its meeting with DBRUP, the Company discussed the specific design and success criteria of the comparative wear study, which is intended to demonstrate adequate adhesion via non-inferiority of Twirla to Xulane, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. The Company has initiated a crossover wear study in approximately 80 healthy women with a Body Mass Index (BMI) of less than 35 kg/m2 who will be randomized to wear either Twirla or Xulane for the first week and then switched to the patch not initially worn for the second week.

The Company confirmed that its current plan is to complete the comparative wear study in the first quarter of 2019 and to resubmit the Twirla new drug application in the first half of 2019, which provides it the opportunity to receive approval by the end of 2019. The FDA has previously informed the Company that in connection with its review of the Twirla NDA, the FDA plans to bring the safety and efficacy of Twirla to an Advisory Committee. The Company also expects that the FDA will conduct a pre-approval inspection of the Company s third-party manufacturer s facility, which must be successfully completed prior to approval.

The Company also confirmed that it believes that its unaudited cash and cash equivalents as of December 31, 2018, will be sufficient to meet its projected operating requirements into the second quarter of 2019, which will include completion of the comparative wear study. The Company will require additional capital to fund its operating needs for the remainder of the second quarter of 2019 and beyond, including among other items, preparation for an anticipated Advisory Committee meeting to discuss safety and efficacy of Twirla, the completion of its commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates.

A copy of the Company s press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

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

(d) **Exhibits.**

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated January 10, 2019.

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 10, 2019

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