AGILE THERAPEUTICS INC
Form 8-K
October 09, 2018

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

October 9, 2018

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 October 9, 2018, Agile Therapeutics, Inc. (the Company) issued a press release announcing the decision of the U.S. Food and Drug Administration s, or FDA s, Office of New Drugs, or OND, regarding the Company s formal dispute resolution request. In the OND decision, received by the Company on October 4, 2018, OND formally denied the Company s appeal and provided a path forward without the need to reformulate Twirla or conduct a bioequivalence study between formulations, as previously suggested by the Division of Bone, Reproductive and Urological Products, or DBRUP. OND suggested that the Company conduct a wear study to evaluate whether Twirla demonstrates generally similar adhesion performance Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, a product the FDA considers to have acceptable adhesion. If this result is demonstrated, OND stated that the study would support the conclusion of adequate Twirla adhesion. The path forward does not address efficacy. Rather, if the wear study is successful, Twirla s safety and efficacy, including the Pearl Index, will need to be reviewed by the FDA. This is an issue that DBRUP plans to bring to Advisory Committee after the adhesion issue has been resolved. The Company plans to meet with the FDA to discuss the specifics of the proposed wear study as soon as possible. After agreeing on the parameters of the wear study with the FDA, the Company anticipates providing a further business update, which will review the Company s cash guidance and planned resubmission timeline.

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 October 9, 2018.

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: October 9, 2018	By:	/s/ Alfred Altomari
	Name:	Alfred Altomari
	Title:	Chairman and Chief Executive Officer