AGILE THERAPEUTICS INC
Form 8-K
May 18, 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

May 15, 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 May 18, 2018, Agile Therapeutics, Inc. (the Company) issued a press release announcing the results of the Company s April 16, 2018 Type A meeting (the Type A Meeting) with the U.S. Food and Drug Administration (the FDA). The Company had the Type A Meeting to discuss the complete response letter dated December 21, 2017 (the CRL) that the FDA issued in connection with the June 26, 2017 New Drug Application (NDA) resubmission for the Company s investigational low dose, non-daily combination hormonal contraceptive patch, Twirla (AG200-15). The Company received the final meeting minutes from the FDA on May 15, 2018.

In the minutes, the FDA informed the Company that it continues to have significant concerns regarding the adhesion of Twirla, which the FDA believes cannot be addressed through the Company s proposed patient compliance programs. The FDA recommended that the Company should address the Twirla adhesion properties by reformulating the transdermal system; conducting a formal adhesion study with the new formulation; and demonstrating bioequivalence to the data and information for the original formulation. The FDA advised the Company that, after the Company satisfies the FDA s questions on adhesion and adequately bridges to the findings in the SECURE Phase 3 trial, it anticipates discussing the safety and efficacy of Twirla at an advisory committee meeting to obtain input on whether the benefits outweigh the risks. In the absence of a finding of bioequivalence, the Company would need to conduct a new Phase 3 study with the new formulation. Finally, the FDA provided guidance on a path forward for addressing manufacturing issues related to Twirla, which path is largely based on the materials the Company had previously submitted in December 2017.

The Company will continue to evaluate all of its options on next steps and expects it will pursue formal dispute resolution. The Company will provide an update when it moves forward. In the Company s Quarterly Report on Form 10-Q for the period ended March 31, 2018, the Company disclosed that it believes its cash and cash equivalents as of March 31, 2018, will be sufficient to meet its operating requirements through the end of 2018. In light of feedback from the FDA, the Company is re-evaluating its business plan to identify ways to extend its ability to fund its operations even further.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Agile Therapeutics, Inc. dated May 18, 2018.

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: May 18, 2018	By:	/s/ Alfred Altomari
	Name:	Alfred Altomari
	Title:	Chairman and Chief Executive Officer