

AGILE THERAPEUTICS INC
Form 8-K
July 24, 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

July 20, 2018

Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36464
(Commission
File Number)

23-2936302
(IRS Employer
Identification No.)

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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:

- ☐ 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)).

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 July 24, 2018, Agile Therapeutics, Inc. (the Company) issued a press release announcing the decision of the Office Director (the Director) of the Office of Drug Evaluation III (ODE III) of the U.S. Food and Drug Administration (the FDA) regarding the Company's formal dispute resolution request. In the ODE III decision, received by the Company on July 20, 2018, the Director affirmed the position of the Division of Bone, Reproductive and Urologic Products and denied the Company's appeal of the December 21, 2017 Complete Response Letter in relation to the New Drug Application for Twirla®. The Company intends to appeal the ODE III decision to the FDA's Office of New Drugs.

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	<u>Agile Therapeutics, Inc. Press Release dated July 24, 2018.</u>

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: July 24, 2018

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