

AGILE THERAPEUTICS INC  
Form 8-K  
December 22, 2017

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(D)**  
**of the Securities Exchange Act of 1934**

**December 21, 2017**

Date of report (Date of earliest event reported)

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**Agile Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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 December 22, 2017, Agile Therapeutics, Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) dated December 21, 2017 in response to the New Drug Application (NDA) resubmission for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15).

The Company also hosted a conference call on December 22, 2017, at 8:00 a.m. Eastern Time to discuss the regulatory update.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and a copy of the Company's script to the conference call is attached hereto as Exhibit 99.2, and each is hereby incorporated by reference herein.

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

(d) Exhibits.

| Exhibit<br>Number | Description                                                                      |
|-------------------|----------------------------------------------------------------------------------|
| 99.1              | <u>Press release issued by Agile Therapeutics, Inc. dated December 22, 2017.</u> |
| 99.2              | <u>Script to Conference Call held on December 22, 2017</u>                       |

**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: December 22, 2017

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