

AGILE THERAPEUTICS INC
Form 8-K
November 01, 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 26, 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 1.01. Entry into a Material Definitive Agreement.

On October 26, 2018, Agile Therapeutics, Inc. (the Company) entered into a Clinical Research Agreement (CRA) with TKL Research, Inc. (TKL) to conduct clinical research services from time to time at the request of the Company. The Company intends to utilize the CRA to perform a comparative wear study between Twirla® (AG200-15), the Company's investigational non-daily, low-dose combination hormonal contraceptive patch and Xulane®, the generic version of the previously marketed Ortho Evra® contraceptive patch, in connection with guidance provided by U.S. Food and Drug Administration. The Company and TKL will execute individual statements of work under the CRA that detail the scope and conduct of requested services as well the budget and payment schedule associated with a particular study.

The CRA provides customary terms and conditions, including those for performance of services by TKL in compliance with the applicable statement of work and all applicable laws. The CRA has a term of five years, provided that, the Company may terminate the CRA or any individual statement of work upon 30 days prior written notice to TKL. In addition, either party may terminate the CRA or any applicable statement of work upon 30 days prior written notice for a material breach by the other party. In the event of termination, TKL shall provide termination assistance for a period of 30 days and will be compensated for such assistance on an hourly rate in accordance with the then-existing statement of work.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the CRA, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2018. Readers should review such agreement for a complete understanding of the terms and conditions associated with this transaction.

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

Item 2.02 Results of Operations and Financial Condition

On November 1, 2018, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2018 and an update on the Company's operations for the same period. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	<u>Press release issued by Agile Therapeutics, Inc. dated November 1, 2018.</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: November 1, 2018

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