

# AGILE THERAPEUTICS INC

## **FORM 8-K** (Current report filing)

Filed 03/08/17 for the Period Ending 03/08/17

|             |  |
|-------------|--|
| Address     | 101 POOR FARM ROAD<br>PRINCETON, NJ 08540-1715 |
| Telephone   | 609-683-1880                                   |
| CIK         | 0001261249                                     |
| Symbol      | AGRX   |
| SIC Code    | 2834 - Pharmaceutical Preparations             |
| Industry    | Biotechnology & Medical Research               |
| Sector      | Healthcare                                     |
| Fiscal Year | 12/31  |

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**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**

**March 8, 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.)

**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)).
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**Item 2.02 Results of Operations and Financial Condition**

On March 8, 2017, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2016 and an update on the Company’s operations. 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 Current Report on Form 8-K (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.

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 99.1                      | Press release issued by Agile Therapeutics, Inc. dated March 8, 2017. |

**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: March 8, 2017

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

**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 99.1                      | Press release issued by Agile Therapeutics, Inc. dated March 8, 2017. |

**Agile Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results****Current Business Plan Expected to Extend Cash Position and Fund Operations into Q2 2018**

**PRINCETON, New Jersey, March 8, 2017** - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's health specialty pharmaceutical company today reported financial results for the three months and year ended December 31, 2016 and provided a corporate update for the fourth quarter 2016.

**Fourth quarter 2016 and other recent corporate developments include:**

- In December 2016, the Company announced that it had received net proceeds of approximately \$3.0 million in non-dilutive financing through the State of New Jersey's Technology Business Tax Certificate Transfer Program.
- In January 2017, the Company announced positive top-line results from its Phase 3 SECURE clinical trial of Twirla®, its investigational low-dose combined hormonal contraceptive patch. SECURE was a multicenter, single-arm, open-label, 13 cycle trial that evaluated safety, efficacy and tolerability of Twirla in 2,032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. The Company plans to resubmit its new drug application ("NDA") for Twirla in the first half of 2017 on the basis of the SECURE results and other information relating to the manufacture of Twirla.

"We made significant progress during 2016 with the successful completion of our SECURE Phase 3 clinical trial, which we believe achieved positive top-line results. We continue to advance our plans to file our NDA resubmission for Twirla in the first half of this year. Once filed, we expect the FDA to complete its review within six months, with a potential approval by the end of 2017." said Al Altomari, Chairman and Chief Executive Officer of Agile. "Our priority moving forward is clear, give precedence to our Twirla development activities and prepare for a potential U.S. launch of Twirla. If approved, we look forward to providing women with a new contraceptive option that is designed to offer greater convenience and flexibility for women's busy lives."

**Fourth Quarter Financial Results**

- **Cash and cash equivalents:** As of December 31, 2016, Agile had \$48.8 million of cash and cash equivalents compared to \$34.4 million of cash and cash equivalents as of December 31, 2015. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of December 31, 2016 will be sufficient to meet its operating requirements into the second quarter of 2018. The Company's current business plan assumes resubmission of the NDA for Twirla in the first half of 2017, a six month FDA review of the Company's resubmission, initiation of pre-commercial activities and initiation of validation of its commercial manufacturing process in coordination with the commercialization of Twirla. In the event of unforeseen changes to its planned timelines, the Company has the ability to postpone certain commercial and validation spending in order to continue the funding of its operations into the second quarter of 2018. The Company will require additional capital for the commercial launch of Twirla, if approved, as well as advancing the development of its other product candidates.
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- **Research and development (R&D) expenses:** R&D expenses were \$5.5 million for the quarter ended December 31, 2016 and \$20.9 million for the year ended December 31, 2016, compared to \$6.9 million and \$25.6 million for the comparable periods in 2015. The decrease in R&D expense was primarily due to decreased clinical development expenses as our Phase 3 clinical trial for Twirla moved closer to completion. In July 2016, the Company began preparations for an initial Phase 2 clinical trial examining the use of AG200-SP along with a smaller lower-dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the woman's cycle. The Company has decided to postpone the trial and will continue to evaluate the timing for initiating dosing of the subjects for this Phase 2 clinical trial, which is dependent on available capital resources.
- **General and administrative (G&A) expenses:** G&A expenses were \$2.3 million for the quarter ended December 31, 2016 and \$8.8 million for the year ended December 31, 2016, compared to \$2.3 million and \$7.5 million for the comparable periods in 2015. The increase in G&A expenses was primarily due to increased stock-based compensation expense associated with 2016 stock option grants as well as increased professional fee expense to support public company operations.
- **Net loss:** Net loss was \$5.2 million, or \$0.18 per basic share for the quarter ended December 31, 2016, compared to a net loss of \$3.9 million, or \$0.17 per basic share for the quarter ended December 31, 2015. Net loss per share for the quarter ended December 31, 2016 includes a benefit from income taxes of approximately \$3.0 million, or \$0.11 per basic share related to the sale of our New Jersey net operating losses through the State of New Jersey's Technology Business Tax Certificate Transfer Program. Net loss per share for the quarter ended December 31, 2015 includes a benefit from income taxes of approximately \$6.0 million, or \$0.27 per share related to the sale of our New Jersey net operating losses. Net loss for the year ended December 31, 2016 was \$28.7 million, or \$1.02 per basic share, compared to a net loss of \$30.3 million, or \$1.38 per basic share for the year ended December 31, 2015.
- **Shares Outstanding:** At December 31, 2016, Agile had 28,759,731 shares of common stock outstanding.

### About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that recently completed Phase 3 trials. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adhesion and patient wearability. For more information, please visit the company website at [www.agiletherapeutics.com](http://www.agiletherapeutics.com). The company may occasionally disseminate material, nonpublic information on the company website.

### Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's clinical trials, regulatory submissions, projected cash position and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential

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changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Our statements about the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute the Company's operational and budget plans, and unforeseen events in our clinical and manufacturing development plans; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Agile Therapeutics

Contact: Mary Coleman — 609-356-1921

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**Agile Therapeutics, Inc.**  
**Condensed Balance Sheets**

(in thousands)  
(Unaudited)

|   | December 31,<br>2016 | December 31,<br>2015 |
|---|----------------------|----------------------|
| <b>Assets</b>                               |                      |                      |
| Current assets:                             |                      |                      |
| Cash and cash equivalents                   | \$ 48,750            | \$ 34,395            |
| Prepaid expenses                            | 2,768                | 3,690                |
| Total current assets                        | 51,518               | 38,085               |
| Property and equipment, net                 | 12,330               | 12,318               |
| Other assets                                | 18                   | 18                   |
| Total assets                                | <u>\$ 63,866</u>     | <u>\$ 50,421</u>     |
| <b>Liabilities and stockholders' equity</b> |                      |                      |
| Current liabilities:                        |                      |                      |
| Accounts payable and accrued expenses       | \$ 5,402             | \$ 5,040             |
| Loan payable, current portion               | 5,104                | 2,336                |
| Warrant liability                           | 172                  | 406                  |
| Total current liabilities                   | 10,678               | 7,782                |
| Loan payable, long-term                     | 10,899               | 12,896               |
| <b>Stockholders' equity</b>                 |                      |                      |
| Common stock                                | 3                    | 2                    |
| Additional paid-in capital                  | 235,754              | 194,468              |
| Accumulated deficit                         | (193,468)            | (164,727)            |
| Total stockholders' equity                  | 42,289               | 29,743               |
| Total liabilities and stockholders' equity  | <u>\$ 63,866</u>     | <u>\$ 50,421</u>     |

**Agile Therapeutics, Inc.**  
**Condensed Statements of Operations**

(in thousands, except share and per share amounts)  
(Unaudited)

|   | Three Months Ended December 31, |                   | Year Ended December 31, |                    |
|---|---------------------------------|-------------------|-------------------------|--------------------|
|   | 2016                            | 2015              | 2016                    | 2015               |
| <b>Operating expenses:</b>                  |                                 |                   |                         |                    |
| Research and development                    | \$ 5,514                        | \$ 6,914          | \$ 20,929               | \$ 25,622          |
| General and administrative                  | 2,295                           | 2,251             | 8,792                   | 7,467              |
| Total operating expenses                    | 7,809                           | 9,165             | 29,721                  | 33,089             |
| Loss from operations                        | (7,809)                         | (9,165)           | (29,721)                | (33,089)           |
| Interest expense, net                       | (533)                           | (551)             | (2,329)                 | (2,072)            |
| Change in fair value of warrants            | 66                              | (155)             | 234                     | (110)              |
| Loss on extinguishment of debt              | —                               | —                 | —                       | (1,036)            |
| Loss before benefit from income taxes       | (8,276)                         | (9,871)           | (31,816)                | (36,307)           |
| Benefit from income taxes                   | 3,075                           | 5,972             | 3,075                   | 5,972              |
| <b>Net loss</b>                             | <u>\$ (5,201)</u>               | <u>\$ (3,899)</u> | <u>\$ (28,741)</u>      | <u>\$ (30,335)</u> |
| <b>Net loss per common share:</b>           |                                 |                   |                         |                    |
| Basic and Diluted                           | <u>\$ (0.18)</u>                | <u>\$ (0.17)</u>  | <u>\$ (1.02)</u>        | <u>\$ (1.38)</u>   |
| <b>Weighted-average shares outstanding:</b> |                                 |                   |                         |                    |
| Basic and Diluted                           | <u>28,758,025</u>               | <u>22,296,638</u> | <u>28,273,331</u>       | <u>22,017,229</u>  |