

**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**

February 23, 2023
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.)

500 College Road East, Suite 310
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 filing 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	AGRX	The Nasdaq Capital Market

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

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.

Item 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

Agile Therapeutics, Inc. (the “Company”) has determined that it incorrectly classified certain warrants (the “Warrants”) that were issued to investors in connection with a public offering of the Company’s common stock (“Common Stock”) in October 2021, a registered direct offering of the Company’s preferred stock (“Preferred Stock”) in March 2022 and a public offering of the Company’s Common Stock in July 2022. These Warrants were improperly classified in equity and should have been recorded as liabilities and measured at fair value at each balance sheet date.

On February 23, 2023, the Company’s Audit Committee (the “Audit Committee”) of the Board of Directors of the Company, after consultation with management, concluded that it is appropriate to correct the errors in accounting for the Warrants in the Company’s financial statements for the year ended December 31, 2021 and each of its interim periods ended March 31, 2022, June 30, 2022 and September 30, 2022 (the “Non-Reliance Periods”) included in the associated Annual Report on Form 10-K and Quarterly Reports on Forms 10-Q for each of the Non-Reliance Periods, filed with the Securities Exchange Commission (the “SEC”), by restating such audited and unaudited financial information because the errors in the financial statements are material to the financial statements for each of the Non-Reliance Periods. As a result, the audited and unaudited financial statements for each of the Non-Reliance Periods should no longer be relied on. The Company will disclose in its December 31, 2022 Annual Report on Form 10-K the restated financial statements for each of the Non-Reliance Periods (“Restatements”). Similarly, any previously issued or filed reports, press releases, earnings releases, and investor presentations or other communications describing the Company’s financial statements and other related financial information covering the Non-Reliance Periods should no longer be relied upon.

The Company is currently in the process of determining the exact amounts and full effect of the errors in the financial statements for each of the Non-Reliance Periods. The Company estimates that the net loss was overstated in each period. The Company’s preliminary estimate is that the cumulative effect of these non-cash errors is an understatement of other income and an overstatement of the net loss of \$3.8 million for the year ended December 31, 2021, and \$23.7 million for the nine-month period ended September 30, 2022; however, such amounts are subject to revision as the Company finalizes its analysis. The Company expects these errors to have no effect on the Company’s previously reported revenue, operating expenses, cash flows or cash.

The Company is currently working to complete the filing of its December 31, 2022 Annual Report on Form 10-K as soon as practicable, which will include the Restatements.

Management is assessing the effect of these Restatements on the Company’s internal control over financial reporting and its disclosure controls and procedures. The Company expects to report at least one material weakness following completion of its analysis of the cause of these Restatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis. The existence of one or more material weaknesses precludes a conclusion by management that the Company’s disclosure controls and procedures and internal control over financial reporting are effective. As a result of the material weakness or material weaknesses, the Company believes that its internal control over financial reporting was not effective, and its disclosure controls and procedures were not effective for the Non-Reliance Periods.

The Company’s management and the Audit Committee have discussed the matters described in this Item 4.02 with its independent registered public accounting firm, Ernst & Young LLP.

Forward-Looking Statements: This Current Report on Form 8-K contains “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The Company advises caution in reliance on forward-looking statements. Forward-looking statements include, without limitation, the Company’s plans related to restatement of the financial statements as of and for each of the quarterly and year to date periods ended December 31, 2021, March 31, 2022, June 30, 2022, and September 30, 2022, and the Company’s estimates related to the errors included in the financial statements covering the Non-Reliance Periods. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those implied by forward-looking statements, including the outcome of the Company’s completion of the quantification and evaluation of the specific impact of the errors related to accounting treatment of the Warrants in the Company’s financial results and previously issued financial

statements, including the possibility of material adjustments thereto, the discovery of additional and unanticipated information during the procedures required to be completed before the Company is able to file its Annual Report on Form 10-K for the year ended December 31, 2022; and the application of accounting or tax principles in an unanticipated manner. See also additional risk factors set forth in the Company's periodic filings with the SEC, including, but not limited to, those risks and uncertainties listed in the section entitled "Risk Factors," in the Company's Annual Report on Form 10-K filed with the SEC. All forward-looking statements in this Current Report on Form 8-K are based on information available to the Company as of the date of this filing. The Company expressly disclaims any obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Item 8.01. Other Information.

On February 27, 2023, the Company issued a press release announcing that it has received notification from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") granting the Company's request for a 180-day extension to regain compliance with the minimum \$1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). The Company now has until August 14, 2023, to meet the Bid Price Requirement. A copy of the Company's press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated February 27, 2023.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: February 27, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

AGILE THERAPEUTICS GRANTED 180-DAY EXTENSION BY NASDAQ TO MEET THE MINIMUM BID PRICE REQUIREMENT

PRINCETON, N.J., February 27, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX) (“Agile” or the “Company”), a women's healthcare company, today announced that it has received written notification from the Listing Qualifications Department of the Nasdaq Stock Market LLC (“Nasdaq”) granting the Company’s request for a 180-day extension to regain compliance under Nasdaq Listing Rule 5550(a)(2). The Company now has until August 14, 2023 to meet the requirement (the “Compliance Date”).

The extension notice from Nasdaq has no immediate effect on the listing or trading of the Company’s shares, which will continue to trade on the Nasdaq Capital Market under the symbol “AGRX.” If at any time prior to the Compliance Date, the bid price of the Company's common stock closes at, or above, \$1.00 per share for a minimum of ten (10) consecutive business days, the Nasdaq Listing staff will provide the Company with written confirmation of compliance and the matter will be closed.

On August 15, 2022, the Company was notified by the Nasdaq Listing Qualifications Department of Nasdaq of its failure to maintain a minimum bid price of \$1.00 per share under Nasdaq Listing Rule 5550(a)(2). The Company originally had 180 calendar days, or until February 13, 2023 to regain compliance. The Company will continue to monitor the bid price of its common stock.

If the Company does not meet the minimum bid price requirement prior to the Compliance Date, the Nasdaq Listing Qualifications Department will notify the Company that its common stock will be subject to delisting. At such time, the Company may appeal the delisting determination to the Nasdaq Hearings Panel. There can be no assurance that if the Company does appeal a subsequent delisting determination, that such appeal will be successful.

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and 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 initial product, Twirla®, (levonorgestrel and ethinyl estradiol) transdermal system, is a non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company’s website, Twitter account ([@agilether](https://twitter.com/agilether)), and [LinkedIn](https://www.linkedin.com/company/agiletherapeutics) account.

Forward-Looking Statements

Certain information contained in this press release includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We may in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “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 changes in circumstances, assumptions, and uncertainties, including statements regarding our ability to regain compliance with the listing requirements of the Nasdaq Capital Market, our projections regarding our net revenue and operating expenses for 2023,

statements regarding our ongoing and planned manufacturing and commercialization of Twirla®, the potential market acceptance and uptake of Twirla, including the increasing demand for Twirla in 2023, our partnership with Afaxys and its ability to promote growth, our product supply agreement with Nurx and its ability to educate patients about Twirla, our connected TV (CTV) campaign and its ability to promote growth, our future plans with respect to additional commercial products, our ability to become cash flow positive, our prospects for future financing arrangements, and our financial condition, growth and strategies. 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. These forward-looking statements are subject to risks and uncertainties including risks related to our ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully enhance the commercialization of and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla and our product candidates, the effects of the ongoing COVID-19 pandemic on our commercialization efforts, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, as well as on our potential customer base, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. 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.

Contact:

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