

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 12, 2022

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 7.01. Regulation FD Disclosure.**

On July 12, 2022, Agile Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release in which it provided updated guidance regarding its expected financial results for the second quarter ended June 30, 2022, which differs from the Company’s previously issued guidance. Based on its current performance and an on-going review of operating expenses, the Company is providing revised guidance indicating that it expects total cycles of Twirla® in the range of 21,000 to 21,500 in the second quarter of 2022, which represents growth of approximately 26% to 30% over the first quarter of 2022. The Company also now projects operating expenses for the second quarter of 2022 in the range of \$11.5 million to \$12.5 million. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

The preliminary results set forth above are based on management’s initial review of our operations for the quarter ended June 30, 2022 and are subject to revision based upon our quarter-end closing procedures and the completion of the review of our quarter-end financial statements. Our independent registered public accounting firm has not reviewed these preliminary financial results. Actual results may differ materially from these preliminary results as a result of the completion of quarter-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized. In addition, these preliminary results are not a comprehensive statement of our financial results for the quarter ended June 30, 2022, should not be viewed as a substitute for full, finalized financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of our results for any future period.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in this Report, including Exhibit 99.1, 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 the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

### **Forward-Looking Statements**

Certain information contained in this Report may include “forward-looking statements.” Our use of terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes may identify these forward-looking statements.

In particular, statements regarding our expectations concerning our second quarter 2022 operating expenses and Twirla total cycles are examples of such forward-looking statements. Such forward-looking statements are subject to important risks and uncertainties, including, but not limited to, risks related to our expectations regarding second quarter 2022 operating expenses and Twirla total cycles, 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 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 other factors, including general economic conditions and regulatory developments, not within the Company’s control.

These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. These forward-looking statements are made only as of the date of this Report and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in “Risk Factors” in the Company’s periodic reports filed with the SEC.

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

**(d) Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a> 104	<a href="#">Press Release dated July 12, 2022</a> Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

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**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: July 13, 2022

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

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## AGILE THERAPEUTICS UPDATES SECOND QUARTER 2022 GUIDANCE

July 12, 2022

*Twirla® Demand Guidance (Total Cycles) Expected to be at Midpoint of Guided Range**Operating Expenses (OPEX) Expected to be Below Guided Range*

PRINCETON, N.J., July 12, 2022 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, announced that it has updated its second quarter 2022 Twirla demand (total cycles) and operating expense (OPEX) guidance that was initially provided on May 24, 2022.

The Company previously guided Twirla demand for the second quarter 2022 to be in the range of 20,000 to 22,000 cycles and now believes demand will be at the mid-point of that range (21,000 to 21,500 cycles), which represents approximately 26% to 30% quarter-on-quarter growth. The updated Twirla demand guidance reflects continued progress made in both the retail and non-retail channels, with the non-retail channel showing significant quarter over quarter growth via the Company's partnership with Afaxys.

Additionally, the Company previously guided OPEX for the second quarter 2022 to be in the range of \$12.5 million to \$13.5 million and now believes OPEX will be below the low end of the previously guided range. The Company expects OPEX will be in the range of \$11.5 million to \$12.5 million, with the change primarily attributable to optimization of the Twirla sales force and marketing efforts to better focus on the most productive territories with high volume and favorable third-party reimbursement as well as the optimization of expense across all general and administrative areas.

The preliminary results set forth above are based on management's initial review of our operations for the quarter ended June 30, 2022 and are subject to revision based upon our quarter-end closing procedures and the completion of the review of our quarter-end financial statements. Our independent registered public accounting firm has not reviewed these preliminary financial results. Actual results may differ materially from these preliminary results as a result of the completion of quarter-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized. In addition, these preliminary results are not a comprehensive statement of our financial results for the quarter ended June 30, 2022, should not be viewed as a substitute for full, finalized financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of our results for any future period.

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**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. Twirla and 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. Twirla<sup>®</sup> and our pipeline products are based on our proprietary transdermal patch technology, called Skinfusion<sup>®</sup>, which is designed to allow drug delivery through the skin. 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's website.

**About Prescription Data**

The Company receives prescription data for Twirla from Symphony Health Solutions, and the data are not created or owned by the Company. Prescription data are available through other subscription services as well, such as IQVIA. The prescription data terms are defined as follows: Twirla cycles dispensed are the number of 3-patch packages dispensed. Each 3-patch package represents one 28-day cycle of therapy. Total Cycles Dispensed represents every cycle dispensed from both retail and non-retail channels. Retail channels include retail pharmacies, mail order, and long-term care while non-retail channels include clinics and hospitals and other entities where prescriptions are dispensed directly to the patient. Total prescriptions (TRx) are the total number of prescriptions dispensed through the retail channels. This represents both new and refill prescriptions. New prescriptions (NRx) are new prescriptions dispensed through retail channels. Refill prescriptions (RRx) are refill prescriptions filled through retail channels. Total prescribers are the cumulative number of prescribers whose prescriptions were filled through retail channels since launch.

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### **Forward-Looking Statement**

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 financial status, including our expectations regarding second quarter 2022 operating expenses and Twirla total cycles, the growth of Twirla and the momentum of such growth, the success of our key initiatives and their effect on our results, and the execution of the Company’s commercial plan. 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 the preparation and finalization of our second quarter 2022 financial results, our ability maintain regulatory approval of Twirla, our ability to successfully commercialize Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, 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: Matt Riley Head of Investor Relations [mriley@agiletherapeutics.com](mailto:mriley@agiletherapeutics.com)

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