

**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**

April 28, 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 2.02 Results of Operations and Financial Condition.

On April 28, 2023, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing preliminary expectations for the first quarter of 2023 Twirla demand, net revenue, and operating expenses (“OPEX”). In the press release, the Company disclosed that it expects total demand to surpass 45,000 total cycles with retail demand expected to exceed 30,500 total cycles, and non-retail demand expected to exceed 14,000 total cycles, all of which represent at least 20% growth from the fourth quarter of 2022. The Company also disclosed that it expects factory sales to exceed 43,000, remaining approximately flat compared to the fourth quarter of 2022. In addition, the Company disclosed that it expects first quarter 2023 net revenue to be in the range of \$3.8 to \$4.0 million and that it expects first quarter OPEX to be in the range of \$8.3 to \$8.8 million. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1

Because the Company’s financial statements for the quarter ended March 31, 2023 have not yet been finalized, these preliminary statements regarding the Company’s Twirla demand, net revenue, and OPEX are subject to change, and the Company’s actual Twirla demand, net revenue, and OPEX may differ materially from these preliminary estimates. Accordingly, you should not place undue reliance on these preliminary estimates.

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 the 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 [Press Release dated April 28, 2023.](#)

104 Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

Forward-Looking Statements

Certain information contained in this Current Report on Form 8-K 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 expected Twirla demand metrics, net revenue and operating expenses for the first quarter of 2023, our projected net revenue and expected operating expenses for 2023, 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 drive additional retail channel growth in the second half of 2023, 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 the fact that our estimated Twirla demand metrics, net revenue and operating expenses for the first quarter of 2023 are not final and may be subject to change, 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 lingering effects of the 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 regain compliance with

the listing requirements of the Nasdaq Capital Market, 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 circumstance.

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: April 28, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

AGILE THERAPEUTICS ANNOUNCES PRELIMINARY EXPECTATIONS FOR FIRST QUARTER 2023

PRINCETON, N.J., April 28, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced preliminary expectations for first quarter 2023 Twirla® demand, net revenue and operating expenses.

Expected First Quarter 2023 Performance Update (Unaudited)

- First Quarter 2023 Twirla Demand:
 - Total demand is expected to surpass 45,000 total cycles, representing at least 20% growth from the fourth quarter 2022 and a single-quarter record.
 - Retail demand – the Company's most profitable channel – is expected to exceed 30,500 total cycles, also a single-quarter record and an increase of at least 20% from the fourth quarter 2022.
 - Non-retail demand is expected to exceed 14,000 total cycles, an increase of at least 20% from the fourth quarter 2022.
 - Factory sales are expected to exceed 43,000 total cycles and to remain approximately flat compared to the fourth quarter 2022.
 - March 2023 set a single-month record for total demand cycles and the Company expects the momentum to carry into the second quarter 2023.
- First quarter 2023 net revenue is expected to be in the range of \$3.8 to \$4.0 million. First quarter wholesaler inventory levels are expected to decrease by approximately 9 days sales or 24% from December 31, 2022 levels.
- First Quarter 2023 operating expenses ("OPEX") are expected to be in the range of \$8.3 to \$8.8 million, a 5%-10% decrease compared to fourth quarter 2022.

"The preliminary Twirla demand data we have for the first quarter 2023 tell us that we are following a strong second half of 2022 with continued expected growth in key performance areas," said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. "March 2023 appears to be our strongest month in the retail channel, and we expect the Company's telehealth collaboration with Nurx to drive additional retail channel growth in the second half of 2023. We continue to focus on managing our operating expenses and expect our first quarter expenses to be lower than the fourth quarter 2022."

"The first quarter 2023 net revenue projection falls in line with the expectations we shared on our last earnings call. We believe factory sales reflect wholesaler work down of inventory levels, which rose slightly at the end of 2022. Wholesaler purchasing patterns in April 2023, we believe, are signaling that the channel has normalized. The strong start to 2023 demand gives us confidence that the Company can achieve its 2023 goal of net revenue in the range of \$25-\$30 million."

The preliminary results and estimates in this press release are based on management's initial review of our operations for the quarter ended March 31, 2023, and are subject to revision based upon our quarter-end closing procedures and the completion of the external review of our quarter-end financial statements.

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), a 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), and LinkedIn account.

About Twirla®

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

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. Not all prescription demand in the non-retail channel is reported into third parties like Symphony Health Solutions and IQVIA. The factory sales reported from Twirla wholesalers do include sales to the non-retail channel and, therefore, the Company believes factory sales more closely represent the total demand for Twirla across all channels.

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