

**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**

**May 11, 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 May 11, 2023, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended March 31, 2023 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 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**

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99.1 [Press Release dated May 11, 2023.](#)

104 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: May 11, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

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**AGILE THERAPEUTICS REPORTS FIRST QUARTER 2023 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE**

*Twirla Delivers Single-Quarter Records for Retail and Non-Retail Demand; Both Channels Up 20% in First Quarter 2023 vs Fourth Quarter 2022*

*Total OPEX down 8% in First Quarter 2023 vs Fourth Quarter 2022*

*Company Reaffirms Expected Full Year 2023 Net Revenue in Range of \$25-\$30 Million*

*Management to Host Conference Call Today, Thursday, May 11, 2023 at 4:30 p.m. ET*

PRINCETON, N.J., May 11, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2023 and provided a corporate update.

"We are pleased to report another successful quarter for Twirla®. We continue to be encouraged by Twirla net revenues to date, along with Twirla demand continuing to grow at double-digit rates," said Agile Therapeutics' Chairperson and Chief Executive Officer Al Altomari. "Looking ahead to the second quarter 2023, we expect to see meaningful quarter-over-quarter growth in net revenue, factory sales and demand while continuing to manage our operating expenses. This is the formula that is driving our confidence in our ability to achieve 2023 net revenue in the range of \$25-\$30 million."

***First Quarter Performance Updates***

- **Twirla delivered \$3.8 million in net revenue for the first quarter 2023.** This was an increase of 117% from the \$1.8 million reported for the first quarter 2022 and a decrease of 5% from the \$4.0 million reported for the fourth quarter 2022. Net revenue results for the first quarter of 2023 reflect flat factory sales quarter on quarter due to a wholesaler work down of inventory levels, which rose at the end of 2022, and a slightly higher mix of non-retail sales which represent higher gross-to-net deductions.
    - Continued Twirla Demand Growth
      - **Twirla demand for the first quarter 2023 was 45,036 total cycles, a 20% increase from the fourth quarter 2022 and a 170% increase from the first quarter 2022.**
        - Retail demand, which is the Company's most profitable channel, was 30,576 total cycles in the first quarter 2023, a 20% increase from the fourth quarter 2022 and a single-quarter record.
        - Non-retail demand for the first quarter 2023 was 14,460 total cycles, also a single-quarter record and an increase of 20% from the fourth quarter 2022.
    - Twirla Factory Sales
      - **Twirla factory sales for the first quarter 2023 were 43,446 total cycles, remaining flat compared to the fourth quarter 2022 and a 158% increase from the first quarter 2022.**
      - Wholesaler inventory levels decreased in the first quarter 2023 by 24% from December 31, 2022.
    - Company Operating Expenses
      - **First quarter GAAP operating expenses were \$8.5 million for 2023, a decrease of 8% from the \$9.2 million reported for the fourth quarter 2022 and a 46% decrease from the first quarter 2022.**
      - The Company plans to continue to actively manage its operating expenses and expects operating expenses for the full year 2023 to be lower than full year 2022.
  - First quarter 2023 improvements in Twirla demand reflect a continued increase of patient utilization in
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both the retail and non-retail channels.

- Collaboration with Afaxys
  - **Non-retail factory sales in the first quarter of 2023 were 17,790, a 15% increase from the 15,420 non-retail cycles sold in the fourth quarter 2022.**
  - The meaningful non-retail channel growth is the product of Afaxys' efforts to expand Twirla in the Planned Parenthood network.

#### **Potential Future Upside from Twirla Business Plan**

- The Company remains focused on achieving its key goals of growing Twirla, attaining 2023 net revenue in the range of \$25-\$30 million and, ultimately, generating positive cash flow. The Company remains confident it can accomplish these key goals by:
  - Targeting Promotional Efforts on Five Key States
    - The Company continues to focus its Twirla promotional efforts on five states that have high levels of reimbursement potential for Twirla and are estimated to reach 45% of U.S. women between the ages of 18 and 24.
  - Increasing Footprint in Telemedicine
    - Beginning in the second quarter 2023, the Company expects to see an impact in the retail channel from its collaboration with female telehealth leader Nurx, as Twirla becomes the only patch offered by Nurx's partner pharmacy.
    - Nurx has provided contraception to more than 1 million patients.
  - Capturing Greater Volume Growth
    - After achieving non-retail factory sales growth of 15% in the first quarter 2023, the Company believes it can continue momentum throughout 2023 from both new and returning orders.
    - The Company believes there is additional potential for Twirla volume growth in this channel based on the reach of the Afaxys customer network, which includes Planned Parenthood and student health centers.
    - The Company also believes it will start to experience increased growth in the retail channel from physicians who gain more clinical experience with Twirla in the Planned Parenthood setting and become more comfortable prescribing Twirla in their other practices.

#### **First Quarter 2023 Financial Results**

- **Net Revenue:** In the first quarter 2023, the Company realized net product sales revenue of \$3.8 million, a decrease of 5% as compared to the fourth quarter 2022 revenue of \$4.0 million. First quarter 2023 net revenue of \$3.8 million represents a 117% increase from the \$1.8 million reported for the comparable period in 2022.
  - **Cost of Goods Sold (COGS):** Cost of goods sold, which consists of direct and indirect costs related to the manufacturing of Twirla, was \$2.0 million for the first quarter 2023, compared to the \$1.7 million reported for the fourth quarter 2022 and \$1.5 million for the comparable period in 2022.
  - **Total operating expenses:** Total operating expenses were \$8.5 million for the first quarter 2023, compared to \$9.2 million for the fourth quarter 2022 and \$15.8 million for the comparable period in 2022.
  - **Cash:** As of March 31, 2023, the Company had \$4.4 million of cash, compared to \$5.2 million of cash and cash equivalents as of the end of the fourth quarter 2022. In addition to the at-the-market (ATM)
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arrangement, the Company will continue to evaluate all available options to finance the Company and continue to explore all opportunities that can potentially accelerate the timeline to generating positive cash flow.

- **GAAP Net Loss:** GAAP net loss was \$5.4 million, or \$5.91 per share, for the first quarter 2023, compared to a GAAP net loss of \$3.9 million, or \$4.76 per share, for the fourth quarter 2022 and a GAAP net loss of \$10.4 million, or \$166.68 per share, for the comparable period in 2022, respectively. The fair market value remeasurement of warrants resulted in \$1.7 million, \$3.3 million and \$1.4 million in other income for the first quarter 2023, fourth quarter 2022, and first quarter 2022, respectively. The Company expects to continue to see fluctuations in GAAP net income or loss depending on the non-cash accounting adjustments of these warrants.
  - **Non-GAAP Net Loss:** Non-GAAP net loss was \$7.1 million, or \$7.76 per share, for the first quarter 2023, compared to a non-GAAP net loss of \$7.3 million or \$8.83 per share for the fourth quarter 2022, and a non-GAAP net loss of \$11.8 million, or \$188.91 per share, for the comparable period in 2022. These results reflect the exclusion of the fair market value remeasurement of warrants of \$1.7 million for the first quarter 2023, \$3.3 million for the fourth quarter 2022 and \$1.4 million for the first quarter 2022. A reconciliation of non-GAAP to GAAP net loss is provided in the tables accompanying this press release.
  - **Shares Outstanding:** As of March 31, 2023, Agile had 932,101 shares outstanding and 912,044 weighted average shares of common stock outstanding, as adjusted for the 1-for-50 reverse stock split implemented by Agile on April 10, 2023.
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## Conference Call and Webcast

Date	Thursday, May 11, 2023
Time	4:30 p.m. ET
Webcast (live and archived)	Events & Presentations
Registration Link	Register Here

A live webcast of the conference call may be accessed via the Investor Relations portion of the Agile Therapeutics website at <https://ir.agiletherapeutics.com/events-and-presentations>.

**To participate in the live conference call via telephone, please register here.** Upon registering, a dial-in number and unique PIN will be provided to join the conference call.

### 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<sup>®</sup>, (levonorgestrel and ethinyl estradiol), a transdermal system, is a non-daily prescription contraceptive. Twirla is 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, Twitter account (@agilether), and LinkedIn account.

### About Twirla<sup>®</sup>

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/m<sup>2</sup> 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/m<sup>2</sup> before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m<sup>2</sup>. 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. Unless otherwise noted, the prescription data results reported in this press release are reported as of March 31, 2022, by Symphony Health Solutions. 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

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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.

### **Use of Non-GAAP Financial Measures**

To supplement our consolidated financial statements, which are prepared and presented in accordance with U.S. generally accepted accounting principles (GAAP), we use non-GAAP operating expenses and non-GAAP net loss to measure our financial performance. We define the term non-GAAP operating expenses as GAAP operating expenses excluding one-time, non-cash charges incurred in connection with the loss on disposition of assets. We define the term non-GAAP net loss as GAAP net loss excluding recurring unrealized gains or losses pertaining to liability classified warrants and one-time non-cash charges incurred in connection with the loss on disposition of assets. We believe that the presentation of these non-GAAP financial metrics provides useful information about our operating results, enhances the overall understanding of past financial performance and future prospects, allows for greater transparency with respect to metrics used by our management in its financial and operational decision-making and produces a useful measure for period-to-period comparisons of our business.

The presentation of these non-GAAP financial measures are not intended to be a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP and may be different from non-GAAP financial measures used by other companies, and therefore, may not be comparable among companies. We believe the presentation of these non-GAAP financial measures provides meaningful supplemental information regarding our performance; however, we urge investors to review the reconciliation of this financial measures to the comparable GAAP financial measures included in the accompanying tables, and not to rely on any single financial measure to evaluate our business.

### **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 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 prospects for future financing arrangements and ability to generate positive cashflow, our expected net revenue and operating expenses for 2023, 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 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 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

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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 & Corporate Communications

[mriley@agiletherapeutics.com](mailto:mriley@agiletherapeutics.com)

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**Agile Therapeutics, Inc.**  
**Balance Sheets**  
(Unaudited)  
(in thousands, except par value and share data)

	March 31, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,429	\$ 5,246
Accounts receivable, net	3,123	3,377
Inventory, net	2,211	1,332
Prepaid expenses and other current assets	1,143	1,403
<b>Total current assets</b>	<b>10,906</b>	<b>11,358</b>
Property and equipment, net	151	177
Right of use asset	628	695
Other non-current assets	2,012	2,012
<b>Total assets</b>	<b>\$ 13,697</b>	<b>\$ 14,242</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Long-term debt, current portion	\$ 1,508	\$ 1,426
Accounts payable	10,358	7,734
Accrued expenses	6,310	3,908
Lease liability, current portion	330	319
<b>Total current liabilities</b>	<b>18,506</b>	<b>13,387</b>
Lease liabilities, long-term	378	466
Warrant liability	4,247	5,934
<b>Total liabilities</b>	<b>23,131</b>	<b>19,787</b>
<b>Stockholders' deficit</b>		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at March 31, 2023 and no shares issued and outstanding at December 31, 2022	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 932,101 and 859,402 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	404,658	403,157
Accumulated deficit	(414,092)	(408,702)
<b>Total stockholders' deficit</b>	<b>(9,434)</b>	<b>(5,545)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 13,697</b>	<b>14,242</b>

**Agile Therapeutics, Inc.**  
**Statement of Operations**  
(in thousands, except share and per share data)

	Three Months Ended	
	March 31, (Unaudited)	
	2023	2022
Revenues, net	\$ 3,813	\$ 1,761
Cost of product revenues	2,003	1,527
Gross profit	1,810	234
<b>Operating expenses:</b>		
Research and development	\$ 763	\$ 1,257
Selling and marketing	4,670	10,553
General and administrative	3,085	3,997
Total operating expenses	8,518	15,807
Loss from operations	(6,708)	(15,573)
<b>Other income (expense)</b>		
Interest income	33	1
Interest expense	(402)	(872)
Unrealized gain on warrant liability	1,687	1,384
Total other income (expense), net	1,318	513
Loss before benefit from income taxes	(5,390)	(15,060)
Benefit from income taxes	—	4,675
Net loss	\$ (5,390)	\$ (10,385)
Net loss per share (basic and diluted)	\$ (5.91)	\$ (166.68)
Weighted-average common shares (basic and diluted)	912,044	62,304

**Agile Therapeutics, Inc.**  
**Reconciliation of GAAP Operating Expenses to Non-GAAP Operating Expenses**  
**(Unaudited)**  
**(in thousands)**

	Three Months Ended					
	3/31/2023	12/31/2022	9/30/2022	6/30/2022	3/31/2022	12/31/2021
GAAP Operating expenses	\$ 8,518	9,219	20,285	11,293	15,807	18,170
Non-GAAP adjustment: Loss on disposition of assets	-	-	11,122	-	-	-
Non-GAAP operating expenses	\$ 8,518	9,219	9,163	11,293	15,807	18,170

**Agile Therapeutics, Inc.**  
**Reconciliation of Net Loss (GAAP) to adjusted Net Loss (non-GAAP)**  
**(Unaudited)**  
**(in thousands)**

	Three Months Ended		
	3/31/2023	3/31/2022	12/31/2022
GAAP Net Loss	\$ (5,390)	(10,385)	\$ (3,929)
Unrealized gain on warrant liability	1,687	1,384	3,349
Loss on disposition of assets	-	-	-
Non-GAAP Net Loss	\$ (7,077)	(11,769)	\$ (7,278)
Non-GAAP Net Loss Per Share	\$ (7.76)	(188.91)	\$ (8.83)
Weighted avg shares	912,044	62,304	824,651