

**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 15, 2024**

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
N/A	N/A	None

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 15, 2024, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended March 31, 2024 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.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release dated May 15, 2024.</a>
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 15, 2024

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

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**AGILE THERAPEUTICS REPORTS FIRST QUARTER 2024 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE**

*First Quarter Net Revenue Increased 58% and Factory Sales Increased 3% from Fourth Quarter 2023*

*Twirla First Quarter 2024 Demand Rebounded 18% from Fourth Quarter 2023*

PRINCETON, N.J., May 15, 2024 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Pink: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2024 and provided a corporate update.

“We are excited about the start of 2024, which saw a rebound in demand, factory sales and net sales in the first quarter from our fourth quarter 2023 results. We plan to continue to focus on executing our business plan, which we believe can continue to grow Twirla and enable us to manage our operating expenses,” said Agile Therapeutics Chairperson and Chief Executive Officer Al Altomari. “We think there are still areas of growth in our five-state focus, expanding our reach in telemedicine and expanding our relationships with planned parenthoods. Our goal is to find new ways to advance our growth plan for Twirla and increase shareholder value and we plan to explore all strategic opportunities, both internally and externally, that can help us reach our goal.”

***First Quarter 2024 Performance Updates***

- **Net Revenue: Twirla delivered \$5.7 million in net revenue for the first quarter of 2024.** This was an increase of 50% from the \$3.8 million reported for the first quarter of 2023. The first quarter 2024 increase in net revenue was primarily due to increased demand.
  - **First quarter 2024 net revenue reflects performance in the following key areas:**
    - Continued Twirla Demand Growth
      - **Twirla demand for the first quarter 2024 was 81,088 total cycles, a 18% increase from the fourth quarter 2023 and a 80% increase from the first quarter 2023.**
      - Retail demand was 43,748 total cycles in the first quarter of 2024, an increase of 8% from the fourth quarter 2023 and a 43% increase from the first quarter 2023.
      - Non-retail demand for the first quarter 2024 was 37,340 total cycles, an increase of 32% from the fourth quarter 2023 and a 158% increase from the first quarter 2023.
    - Twirla Factory Sales
      - **Twirla factory sales for the first quarter 2024 were 70,662 total cycles, a 3% increase from the fourth quarter 2023 and a 63% increase from the first quarter 2023.**
    - Company Operating Expenses
      - **First quarter 2024 operating expenses were \$6.8 million, a 24% increase from the fourth quarter 2023, and a decrease of 20% from the \$8.5 million reported for the first quarter 2023.**
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- **Trading on the “Over the Counter” Market**
  - As of March 26, 2024, the Company’s common stock is now trading on the “over the counter” market operated by the OTC Markets Group under its existing “AGRX” trading symbol. The Company has applied for trading on the OTC-QB market.
  - The Company does not expect the transition to OTC to impact its business operation and it remains focused on executing its business plan while continuing to explore strategic opportunities.
- **Potential for Enhanced Access to Twirla**
  - The Company remains optimistic about the steps being taken by the Biden-Harris Administration to enhance access to no-cost contraception products like Twirla. In January 2024, the Administration announced new guidance to enable expanded access to all FDA-approved contraceptives without cost.
  - Implementation of the new guidance could eliminate financial barriers for contraceptive products like Twirla for an estimated 49 million women.

***First Quarter 2024 Financial Results***

- **Net Revenue:** In the first quarter 2024, the Company realized net product sales revenue of \$5.7 million, a 58% increase from the fourth quarter 2023 and an increase of 50% as compared to the first quarter of 2023 net revenue of \$3.8 million.
  - **Cost of Goods Sold (COGS):** Cost of goods sold, which consists of direct and indirect costs related to the manufacturing of Twirla, were \$1.7 million for the first quarter 2024 compared to the \$2.2 million for the fourth quarter 2023 and compared to the \$2.0 million for the first quarter 2023.
  - **Total operating expenses:** Total GAAP operating expenses were \$6.8 million for the quarter ended March 31, 2024, compared to the \$5.5 million for the fourth quarter 2023 and compared to \$8.5 million for the comparable period in 2023 – a decrease of 20%.
  - **GAAP Net income (loss):** GAAP net income was \$1.3 million, or \$0.28 per share, for the quarter ended March 31, 2024, compared to a GAAP net loss of \$4.5 million, or \$1.51 per share, for the fourth quarter 2023 and compared to a GAAP net loss of \$5.4 million, or \$5.91 per share, for the comparable period in 2023.
  - **Non-GAAP Net Loss:** Non-GAAP net loss was \$2.9 million, or \$0.63 per share, for the quarter ended March 31, 2024, compared to a non-GAAP net loss of \$4.3 million, or \$1.46 per share, for the fourth quarter 2023 and compared to a non-GAAP net loss of \$7.1 million, or \$7.76 per share, for the comparable period in 2023. These results reflect the exclusion of the \$4.2 million in other income for the first quarter of 2024, \$0.1 million in other loss for the fourth quarter 2023, and \$1.7 million in other income for the first quarter of 2023, all resulting from the change in value of the Company’s warrant liability. A reconciliation of non-GAAP to GAAP net loss is provided in the tables accompanying this press release.
  - **Cash:** As of March 31, 2024, the Company had \$2.6 million of cash and cash equivalents, compared to \$2.5 million of cash and cash equivalents as of December 31, 2023. 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.
  - **Shares Outstanding:** As of March 31, 2024, Agile had 6,856,229 shares outstanding and 4,631,902 weighted average shares of common stock outstanding for the three months ended March 31, 2024.
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**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 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 December 31, 2023, by Symphony Health Solutions. The prescription data terms are defined as follows: Twirla cycles dispensed are the number of 3-patch packages dispensed.

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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.

#### **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 net loss to measure our financial performance. We define the term non-GAAP net loss as GAAP net loss excluding recurring unrealized gains or losses pertaining to liability classified warrants. 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 2024, 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 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 raise additional capital, ability to pay our obligations as they become due, ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain, the ability of

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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, 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, 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:**

Agile Therapeutics Investor Relations

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

	March 31, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,615	\$ 2,557
Accounts receivable, net	4,813	3,392
Inventory, net	3,748	2,738
Prepaid expenses and other current assets	811	843
<b>Total current assets</b>	<b>11,987</b>	<b>9,530</b>
Property and equipment, net	50	75
Right of use asset	335	412
Other non-current assets	238	238
<b>Total assets</b>	<b>\$ 12,610</b>	<b>\$ 10,255</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Long-term debt and notes payable	\$ -	\$ 1,706
Accounts payable	12,620	9,574
Accrued expenses	8,443	9,131
Lease liability, current portion	378	366
<b>Total current liabilities</b>	<b>21,441</b>	<b>20,777</b>
Lease liabilities, long-term	-	100
Warrant liability	1,493	5,696
<b>Total liabilities</b>	<b>22,934</b>	<b>26,573</b>
<b>Stockholders' deficit</b>		
Preferred stock, \$.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at December 31, 2023 and no shares issued and outstanding at December 31, 2022	-	-
Common stock, \$.0001 par value, 300,000,000 shares authorized, 6,856,229 and 2,963,657 issued and outstanding at March 31, 2024 and December 31, 2022, respectively	5	4
Additional paid-in capital	411,555	406,846
Accumulated deficit	(421,884)	(423,168)
<b>Total stockholders' deficit</b>	<b>(10,324)</b>	<b>(16,318)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 12,610</b>	<b>\$ 10,255</b>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>(Unaudited)</b>	
	<b>2024</b>	<b>2023</b>
Revenues, net	\$ 5,716	\$ 3,813
Cost of product revenues	1,680	2,003
Gross profit	<u>4,036</u>	<u>1,810</u>
<b>Operating expenses:</b>		
Research and development	\$ 495	\$ 763
Selling and marketing	3,682	4,670
General and administrative	2,616	3,085
Total operating expenses	<u>6,793</u>	<u>8,518</u>
Loss from operations	(2,757)	(6,708)
<b>Other income (expense)</b>		
Interest income	23	33
Interest expense	(185)	(402)
Unrealized gain on warrant liability	4,203	1,687
Total other income (expense), net	<u>4,041</u>	<u>1,318</u>
Loss before benefit from income taxes	1,284	(5,390)
Benefit from income taxes	-	-
Net income (loss) and comprehensive income (loss)	<u>\$ 1,284</u>	<u>\$ (5,390)</u>
Net income (loss) per share (basic and diluted)	<u>\$ 0.28</u>	<u>\$ (5.91)</u>
Weighted-average common shares (basic and diluted)	<u>4,631,902</u>	<u>912,044</u>
<b>Comprehensive loss:</b>		
Net income (loss)	\$ 1,284	\$ (5,390)
<b>Other comprehensive income:</b>		
Unrealized (loss) gain on marketable securities	-	-
Comprehensive income (loss)	<u>\$ 1,284</u>	<u>\$ (5,390)</u>

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

	Three Months Ended		
	3/31/2024	12/31/2023	3/31/2023
GAAP net income (loss)	\$ 1,284	\$ (4,467)	(5,390)
Unrealized gain (loss) on warrant liability	4,203	(130)	1,687
Non-GAAP net loss	<u>\$ (2,919)</u>	<u>\$ (4,337)</u>	<u>(7,077)</u>
Non-GAAP net loss per share	<u>\$ (0.63)</u>	<u>\$ (1.46)</u>	<u>(7.76)</u>
Weighted-average common shares	<u>4,631,902</u>	<u>2,963,657</u>	<u>912,044</u>

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