

**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**

March 28, 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 March 28, 2024, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 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
99.1	Press Release dated March 28, 2024.
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: March 28, 2024

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

AGILE THERAPEUTICS REPORTS FOURTH QUARTER & FULL YEAR 2023 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Full Year 2023 Net Revenue Increased 80% from 2022 While OPEX Decreased 33%

Twirla Demand and Factory Sales Up 121% and 114% Respectively in 2023 vs 2022

Company Completes Pay-Off of Debt Facility in First Quarter 2024

Twirla Demand Expected to Rebound in First Quarter 2024 from Decreased Demand in Fourth Quarter 2023

Management to Host Conference Call Today, Thursday, March 28, 2024 at 8:30 a.m. ET

PRINCETON, N.J., March 28, 2024 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Pink: AGRX), a women's healthcare company, today reported financial results for the three and twelve months ended December 31, 2023 and provided a corporate update.

"2023 was a year for Agile that we believe demonstrated our ability to continue to grow Twirla," said Agile Therapeutics Chairperson and Chief Executive Officer Al Altomari. "We believe we answered questions about our business model's sustainability in 2023 by once again demonstrating meaningful year-over-year growth in net revenue, Twirla demand, and Twirla factory sales while simultaneously keeping operating expenses at responsible levels. We continue to believe in our business model with an emphasis on partnerships to maximize Twirla's growth potential. We will continue to explore any and all strategic opportunities, both internally and externally, that have the ability to maximize Twirla growth and increase shareholder value."

Fourth Quarter & Full Year 2023 Performance Updates

- **Twirla delivered \$19.6 million in net revenue in 2023.** This was an increase of 80% from the \$10.9 million reported for full year 2022. Net revenue for the fourth quarter 2023 was \$3.6 million, a 46% decrease from the third quarter 2023 net revenue of \$6.7 million. The fourth quarter 2024 decrease in net revenue was primarily due to decreased demand and an increase in gross-to-net charges primarily due to increased activity in the Company's Medicaid business, an increase in the Company's returns reserve, and a larger mix of non-retail business.
 - Fourth quarter and full year 2023 net revenue reflects performance in the following key areas:
 - Continued Year-Over-Year Twirla Demand Growth
 - **Twirla demand for full year 2023 was 243,841 total cycles, a 131% increase from the 105,741 total cycles reported for full year 2022.**
 - For the fourth quarter 2023, Twirla demand was 68,793 total cycles, a 7% decrease from the 74,325 total cycles reported for the third quarter 2023.
 - Based on first quarter 2024 activity to date, Twirla January demand numbers (26,464 total cycles) show that the Company achieved the highest number of retail channel cycles in a single month since launch.
 - Additionally, despite being a short month, February total demand (24,729 total cycles) was larger than any single month of the fourth quarter 2023 in both retail and total cycles.
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- **Twirla Factory Sales**
 - Twirla factory sales for the full year 2023 were 248,220 total cycles, a 117% increase from the 114,546 total cycles reported for the full year 2022.
 - For the fourth quarter 2023, Twirla factory sales were 68,580 total cycles, an 8% decrease from the 74,424 total cycles reported for the third quarter 2023.
- **Company Operating Expenses**
 - Full year 2023 operating expenses were \$30.5 million, a decrease of 33% from the \$45.5 million reported for 2022.
 - Fourth quarter 2023 operating expenses were \$5.5 million, a decrease of 33% from the \$8.2 million for the third quarter 2023. This reduction is primarily due to the Company's decision to forgo bonuses for all of 2023 for all employees, including management.

Additional Corporate Updates

- **Elimination of Debt Facility with Perceptive Advisors**
 - In March 2024, the Company announced the payoff of the remaining debt owed to Perceptive Advisors. The Company believes this significant milestone will provide more flexibility on its balance sheet moving forward.
- **Delisting from Nasdaq**
 - On March 25, 2024, the Company announced it received a final delisting notice from Nasdaq due to its failure to regain compliance with the Nasdaq minimum stockholders' equity requirement.
 - 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.

Fourth Quarter & Full Year 2023 Financial Results

- **Net Revenue:** In the fourth quarter 2023, the Company realized net product sales revenue of \$3.6 million, a decrease of 46% as compared to the third quarter 2023 revenue of \$6.7 million. Full year 2023 net revenue was \$19.6 million, a 80% increase from the \$10.9 million reported for full year 2022.
 - **Cost of Goods Sold (COGS):** Cost of goods sold, which consists of direct and indirect costs related to the manufacturing of Twirla, were \$2.2 million for the fourth quarter and \$9.0 million for the full year 2023, compared to the \$1.7 million and \$6.8 million reported for the same periods in
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2022.

- **Total operating expenses:** Total GAAP operating expenses were \$5.5 million for the quarter ended December 31, 2023, compared to \$9.2 million for the comparable period in 2022 – a decrease of 41%. For the full year 2023, GAAP operating expenses were \$30.5 million, compared to \$45.5 million for the full year 2022, representing a 33% decrease year on year.
 - **GAAP Net loss:** GAAP net loss was \$4.5 million, or \$1.51 per share, for the quarter ended December 31, 2023, compared to a GAAP net loss of \$3.9 million, or \$4.76 per share, for the comparable period in 2022. For full year 2023, net loss was \$14.5 million, or \$6.71 a share, compared to \$25.4 million, or \$58.82 per share in the full year 2022.
 - **Non-GAAP Net Loss:** Non-GAAP net loss was \$4.3 million, or \$1.46 per share, for the quarter ended December 31, 2023, compared to a non-GAAP net loss of \$7.3 million, or \$8.82 per share, for the comparable period in 2022. For the full year 2023, non-GAAP net loss was \$21.2 million, or \$9.84 a share, compared to \$39.8 million, or \$92.15 per share in the full year 2022. These results reflect the exclusion of the \$6.8 million in other income for 2023 and \$25.5 million in other income for 2022 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 December 31, 2023, the Company had \$2.5 million of cash, compared to \$5.2 million of cash and cash equivalents as of the end of the fourth quarter 2022. In February 2024, the Company raised \$4.8 million in gross proceeds through a warrant exercise agreement with a holder of the Company's warrants. 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 December 31, 2023, Agile had 2,963,657 shares outstanding and 2,156,726 weighted average shares of common stock outstanding for the year ended December 31, 2023.
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Conference Call and Webcast

Date	Thursday, March 28, 2024
Time	8:30 a.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®, (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 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. 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.

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-termcare 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 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 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 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:

Matt Riley
Head of Investor Relations & Corporate Communications
mriley@agiletherapeutics.com

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,557	\$ 5,246
Accounts receivable, net	3,392	3,377
Inventory, net	2,738	1,332
Prepaid expenses and other current assets	843	1,403
Total current assets	9,530	11,358
Property and equipment, net	75	177
Right of use asset	412	695
Other non-current assets	238	2,012
Total assets	\$ 10,255	\$ 14,242
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt and notes payable	\$ 1,706	\$ 1,426
Accounts payable	9,574	7,734
Accrued expenses	9,131	3,908
Lease liability, current portion	366	319
Total current liabilities	20,777	13,387
Lease liabilities, long-term	100	466
Warrant liability	5,696	5,934
Total liabilities	26,573	19,787
Stockholders' deficit		
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, 2,963,657 and 859,402 issued and outstanding at December 31, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	406,846	403,153
Accumulated deficit	(423,168)	(408,702)
Total stockholders' deficit	(16,318)	(5,545)
Total liabilities and stockholders' deficit	\$ 10,255	\$ 14,242

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

	Three Months Ended		Year Ended	
	December 31, (Unaudited)		December 31,	
	2023	2022	2023	2022
Revenues, net	\$ 3,615	\$ 3,996	\$ 19,593	\$ 10,884
Cost of product revenues	2,191	1,653	8,978	6,836
Gross profit	<u>1,424</u>	<u>2,343</u>	<u>10,615</u>	<u>4,048</u>
Operating expenses:				
Research and development	\$ 54	\$ 352	\$ 2,225	\$ 3,253
Selling and marketing	3,729	6,844	17,769	30,369
General and administrative	1,691	2,023	10,505	11,860
Loss on disposition of assets	-	-	-	11,122
Total operating expenses	<u>5,474</u>	<u>9,219</u>	<u>30,499</u>	<u>56,604</u>
Loss from operations	<u>(4,050)</u>	<u>(6,876)</u>	<u>(19,884)</u>	<u>(52,556)</u>
Other income (expense)				
Interest income	17	30	78	80
Interest expense	(304)	(432)	(1,419)	(3,131)
Unrealized (loss) gain on warrant liability	(130)	3,349	6,760	25,520
Total other income (expense), net	<u>(417)</u>	<u>2,947</u>	<u>5,419</u>	<u>22,469</u>
Loss before benefit from income taxes	<u>(4,467)</u>	<u>(3,929)</u>	<u>(14,465)</u>	<u>(30,087)</u>
Benefit from income taxes	-	-	-	4,675
Net loss	<u>\$ (4,467)</u>	<u>\$ (3,929)</u>	<u>\$ (14,465)</u>	<u>\$ (25,412)</u>
Net loss per share (basic and diluted)	<u>\$ (1.51)</u>	<u>\$ (0.10)</u>	<u>\$ (6.71)</u>	<u>\$ (1.18)</u>
Weighted-average common shares (basic and diluted)	<u>2,963,657</u>	<u>41,232,562</u>	<u>2,156,726</u>	<u>21,610,947</u>
Comprehensive loss:				
Net loss	\$ (4,467)	\$ (3,929)	\$ (14,465)	\$ (25,412)
Other comprehensive income:				
Unrealized (loss) gain on marketable securities	-	-	-	-
Comprehensive loss	<u>\$ (4,467)</u>	<u>\$ (3,929)</u>	<u>\$ (14,465)</u>	<u>\$ (25,412)</u>

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

	Three Months Ended					Twelve Months Ended	
	12/31/2023	9/30/2023	6/30/2023	3/31/2023	12/31/2022	12/31/2023	12/31/2022
GAAP Operating expenses	\$ 5,474	8,185	8,322	8,518	9,219	\$ 30,499	\$ 56,604
Non-GAAP adjustment:							
Loss on disposition of assets	\$ -	-	-	-	-	\$ -	11,122
Non-GAAP operating expenses	\$ 5,474	8,185	8,322	8,518	9,219	\$ 30,499	\$ 45,482

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

	Three Months Ended					Twelve Months Ended	
	12/31/2023	9/30/2023	6/30/2023	3/31/2023	12/31/2022	12/31/2023	12/31/2022
GAAP Net Loss	\$ (4,467)	(799)	(3,809)	(5,390)	(3,929)	\$ (14,465)	\$ (25,412)
Unrealized (loss) gain on warrant liability	(130)	3,529	1,674	1,687	3,349	6,760	25,520
Loss on disposition of assets	-	-	-	-	-	-	(11,122)
Non-GAAP Net Loss	\$ (4,337)	(4,328)	(5,483)	(7,077)	(7,278)	\$ (21,225)	\$ (39,810)
Non-GAAP Net Loss Per Share	\$ (1.46)	(1.47)	(3.10)	(7.76)	(8.82)	\$ (9.84)	\$ (92.15)
Weighted avg shares	2,963,657	2,950,136	1,769,803	912,044	824,651	2,156,726	432,219