

**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**

November 9, 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 November 9, 2023, Agile Therapeutics, Inc., (the “Company”) issued a press release announcing its financial results for the three and nine months ended September 30, 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 November 9, 2023.
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: November 9, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairperson and Chief Executive Officer

AGILE THERAPEUTICS REPORTS THIRD QUARTER 2023 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Twirla Delivers Third Quarter 2023 Net Revenue of \$6.7 Million, a 21% Increase from Second Quarter 2023

Company Announces It Expects to Generate Positive Cash Flow from Operations in First Quarter 2024

Gross Margin Grows to 63% in Third Quarter 2023 from 58% in Second Quarter 2023

Company Reaffirms Expected Full Year 2023 Net Revenue of At Least \$25 Million

Management to Host Conference Call Today, Thursday, November 9, 2023 at 8:30 a.m. ET

PRINCETON, N.J., November 9, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and nine months ended September 30, 2023, and provided a corporate update.

"In the third quarter 2023, we once again achieved all-time highs across several leading indicators, including net revenue, Twirla demand, factory sales, and gross margin," said Agile Therapeutics' Chair and Chief Executive Officer Al Altomari. "We believe our continued focus on revenue growth and fiscal discipline can help us achieve our 2023 net revenue goal of at least \$25 million, lead to continued improvement in our gross margin, and, in turn, help us begin to generate positive cash flow from operations in the first quarter 2024. We believe this plan will put us in the position of having options about how to invest our future cash."

Third Quarter Performance Updates

- **Twirla delivered \$6.7 million in net revenue for the third quarter 2023.** This was an increase of 122% from the \$3.0 million reported for the third quarter 2022 and an increase of 21% from the \$5.5 million reported for the second quarter 2023. Net revenue results for the third quarter of 2023 reflect factory sales growth across all channels and an improved mix of sales which led to lower gross-to-net deductions.
 - Continued Twirla Demand Growth
 - **Twirla demand for the third quarter 2023 was 74,325 total cycles, a 33% increase from the second quarter 2023 and a 147% increase from the third quarter 2022.**
 - Retail demand, which is the Company's most profitable channel, was 40,196 total cycles in the third quarter 2023, a 13% increase from the second quarter 2023.
 - Non-retail demand for the third quarter 2023 was 34,129 total cycles and an increase of 71% from the second quarter 2023.
 - Twirla Factory Sales
 - **Twirla factory sales for the third quarter 2023 were 74,424 total cycles, an increase of 20% compared to the second quarter 2023 and a 125% increase from the third quarter 2022.**
 - The Company believes wholesaler inventory levels have now stabilized in 2023.
-

- o Company Operating Expenses
 - **Third quarter GAAP operating expenses (“OPEX”) were \$8.2 million for 2023, a decrease of 2% from the \$8.3 million reported for the second quarter 2023 and an 11% decrease from the third 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 the full year 2022.
- o Gross Margin
 - **In the third quarter 2023, the Company generated gross profit of approximately \$4.2 million, or gross margin of 63%, compared to \$3.2 million, or gross margin of 58%, in the second quarter 2023.**

Plan for Continued Growth

- It has been approximately one year since the Company recalibrated its business plan to put an emphasis on partnerships that maximize Twirla growth while simultaneously managing Company OPEX levels.
 - Compared to the first nine months of 2022, the recalibrated business plan has delivered consistent improvement during the first nine months of 2023:
 - o Net revenue growth of 132%
 - o Twirla demand growth of 156%
 - o OPEX reduction of 31%
 - Additional growth and upside potential are expected from the following areas:
 - o Furthering Promotional Efforts in 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 over 45% of U.S. women between the ages of 18 and 24.
 - The Company believes there is more room for growth in these states through increased penetration into the current prescriber base, as well as focusing on current non-writers of Twirla.
 - o Additional Volume from the Afaxys Customer Network
 - While the Company grew non-retail demand 71% in the third quarter 2023 compared to second quarter 2023, it estimates that it currently reaches less than 20% of the total Afaxys customer network and plans to tap into additional volume moving forward.
 - o Advancing Twirla’s Availability Through Telemedicine Platforms
 - Advancing Twirla’s availability through telemedicine platforms such as Nurx, TwentyEight Health, and Pandia are all part of the Company’s strategy to sustain growth in the retail channel.
-

Third Quarter 2023 Financial Results

- **Net Revenue:** In the third quarter 2023, the Company realized net product sales revenue of \$6.7 million, an increase of 21% as compared to the second quarter 2023 revenue of \$5.5 million. Third quarter 2023 net revenue of \$6.7 million represents a 122% increase from the \$3.0 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 sold, was \$2.5 million for the third quarter 2023, compared to the \$2.3 million reported for the second quarter 2023 and \$1.4 million for the comparable period in 2022.
 - **Total operating expenses:** Total operating expenses were \$8.2 million for the third quarter 2023, compared to \$8.3 million for the second quarter 2023 and \$9.2 million for the comparable period in 2022.
 - **Cash:** As of September 30, 2023, the Company had \$2.9 million of cash, compared to \$2.8 million of cash and cash equivalents as of the end of the second quarter 2023. In addition to the Company's existing at-the-market (ATM) 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 \$0.8 million or \$0.27 per share for the third quarter 2023, compared to a GAAP net loss of \$3.8 million, or \$2.15 per share, for the second quarter 2023 and a GAAP net loss of \$5.9 million, or \$8.01 per share, for the comparable period in 2022, respectively. The Company expects to continue to see fluctuations in GAAP net income or loss depending on the non-cash accounting adjustments of its warrants.
 - **Non-GAAP Net Loss:** Non-GAAP net loss was \$4.3 million, or \$1.47 per share, for the third quarter 2023, compared to a non-GAAP net loss of \$5.5 million, or \$3.10 per share for the second quarter 2023, and \$19.7 million, or \$26.58 per share, for the comparable period in 2022. The Company incurred a one-time, non-cash operating expense charge of \$11.1 million in the third quarter 2022 related to the transfer of equipment ownership to Corium, which is reflected in the net loss for the third quarter 2022. The non-GAAP results reflect the exclusion of this charge and of the fair market value remeasurement of warrant liabilities, which resulted in other income of \$3.5 million in the third quarter 2023, \$1.7 million in the second quarter 2023, and \$13.7 million in the third quarter 2022. A reconciliation of GAAP to non-GAAP net loss is provided in the tables accompanying this press release.
 - **Shares Outstanding:** As of September 30, 2023, Agile had 2,277,657 shares outstanding. For the three months ended September 30, 2023, there were 2,950,136 weighted average shares of common stock outstanding.
-

Conference Call and Webcast

Date	Thursday, November 9, 2023
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, 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. Unless otherwise noted, the prescription data results reported in this press release are reported as of September 30, 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 2023 and beyond, our partnerships with Afaxys and Syneos and their 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 full-year 2023, our expectations regarding the generation of positive cash flow in the first quarter 2024, 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 regain 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 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
(Unaudited)
(in thousands, except par value and share data)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,785	\$ 5,246
Accounts receivable, net	4,461	3,377
Inventory, net	2,537	1,332
Prepaid expenses and other current assets	1,866	1,403
Total current assets	11,649	11,358
Property and equipment, net	126	177
Right of use asset	558	695
Other non-current assets	238	2,012
Total assets	\$ 12,571	\$ 14,242
Liabilities and stockholders' deficit		
Current liabilities:		
Long-term debt, current portion	\$ 1,562	\$ 1,426
Notes payable, current portion	502	—
Accounts payable	6,156	7,734
Accrued expenses	6,747	3,908
Lease liability, current portion	342	319
Total current liabilities	15,309	13,387
Lease liabilities, long-term	288	466
Warrant liability	9,095	5,934
Total liabilities	24,692	19,787
Commitments and contingencies (Note 10)		
Stockholders' deficit		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at June 30, 2023 and no shares issued and outstanding at December 31, 2022	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 1,640,805 and 859,402 issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	405,779	403,157
Accumulated deficit	(417,900)	(408,702)
Total stockholders' deficit	(12,121)	(5,545)
Total liabilities and stockholders' deficit	\$ 12,571	\$ 14,242

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues, net	\$ 5,503	\$ 2,126	\$ 9,316	\$ 3,887
Cost of product revenues	2,307	2,231	4,310	3,758
Gross profit	<u>3,196</u>	<u>(105)</u>	<u>5,006</u>	<u>129</u>
Operating expenses:				
Research and development	\$ 703	\$ 856	\$ 1,466	\$ 2,113
Selling and marketing	4,570	7,411	9,240	17,964
General and administrative	3,049	3,026	6,133	7,023
Total operating expenses	<u>8,322</u>	<u>11,293</u>	<u>16,839</u>	<u>27,100</u>
Loss from operations	<u>(5,126)</u>	<u>(11,398)</u>	<u>(11,833)</u>	<u>(26,971)</u>
Other income (expense)				
Interest income	15	2	48	3
Interest expense	(372)	(823)	(773)	(1,695)
Unrealized gain on warrant liability	1,674	7,051	3,361	8,435
Total other income, net	<u>1,317</u>	<u>6,230</u>	<u>2,636</u>	<u>6,743</u>
Loss before benefit from income taxes	<u>(3,809)</u>	<u>(5,168)</u>	<u>(9,197)</u>	<u>(20,228)</u>
Benefit from income taxes	—	—	—	4,675
Net loss and comprehensive loss	<u>\$ (3,809)</u>	<u>\$ (5,168)</u>	<u>\$ (9,197)</u>	<u>\$ (15,553)</u>
Net loss per share (basic and diluted)	<u>\$ (2.15)</u>	<u>\$ (57.29)</u>	<u>\$ (6.85)</u>	<u>\$ (203.76)</u>
Weighted-average common shares (basic and diluted)	<u>1,769,803</u>	<u>90,204</u>	<u>1,343,293</u>	<u>76,331</u>

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

	Three Months Ended				Six Months Ended	
	6/30/2023	3/31/2023	6/30/2022	3/31/2022	6/30/2023	6/30/2022
GAAP Net Loss	\$ (3,809)	(5,390)	(5,168)	(10,385)	\$ (9,197)	(15,553)
Unrealized gain on warrant liability	1,674	1,687	7,051	1,384	3,361	8,435
Loss on disposition of assets	-	-	-	-	-	-
Non-GAAP Net Loss	\$ (5,483)	(7,077)	(12,219)	(11,769)	\$ (12,558)	(23,988)
Non-GAAP Net Loss Per Share	\$ (3.10)	(7.76)	(135.46)	(188.90)	\$ (9.35)	(314.26)
Weighted avg shares	1,769,803	912,044	90,204	62,304	1,343,293	76,331
