

**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 7, 2022
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 7, 2022, the Company issued a press release announcing its financial results for the three months ended September 30, 2022 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 7, 2022.
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 7, 2022

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

AGILE THERAPEUTICS REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Net Revenue Increased 43% from Second Quarter 2022

Largest Quarter-over-Quarter Increase in Net Revenue Achieved by Agile

Non-Retail Channel Twirla Cycles Grew 361% from Second Quarter 2022

Company Expects Business Plan Can Deliver Additional Growth in the Fourth Quarter of 2022 and in 2023

Management to Host Conference Call Today, Monday, November 7, 2022 at 4:30 p.m. ET

PRINCETON, N.J., November 7, 2022 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended September 30, 2022 and provided a corporate update.

"The third quarter is the quarter we expected to be the breakout quarter for both Agile and Twirla and we are thrilled to share the quarter's encouraging results," said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. "Net revenue grew 43% in the quarter – the largest quarter-over-quarter increase we have achieved – and the growth was driven by increasing Twirla demand. This reinforces our confidence in the credibility of our current business plan and we believe the plan can deliver additional growth in the fourth quarter 2022 and in 2023. We are focused on our key goals of growing Twirla and generating positive cash flow, and pursuing opportunities to advance our performance, including exploring business development opportunities."

Third Quarter Performance Updates

- **Twirla delivered \$3.0 million in net revenue for the third quarter 2022.** This was an increase of 43% from the second quarter 2022 – the largest quarter-over-quarter increase the Company has achieved. Net revenue growth reflects improvements in the following key areas:
 - Significant Twirla Demand Growth
 - **Twirla demand for the third quarter was 28,541 total cycles, a 35% increase from the second quarter 2022.**
 - Compared to the third quarter 2021, total demand for Twirla grew by 18,706 total cycles, or 192%.
 - Significant Twirla Factory Sales Growth
 - **Twirla factory sales for the third quarter were 33,282 total cycles, a 54% increase from the second quarter 2022.**
 - Compared to the third quarter 2021, factory sales for Twirla grew by 22,632 total cycles, or 212%.
 - Company Operating Expenses
 - **GAAP Operating expenses for the third quarter 2022 were \$20.3 million. Non-GAAP operating expenses for the third quarter 2022 were \$9.2 million, a 19% decrease from the \$11.3 million reported for the second quarter 2022.**
 - Compared to the third quarter 2021, Non-GAAP operating expenses decreased by \$5.2 million, or 36%.
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- In the fourth quarter 2022, the Company expects operating expenses to be within the range of \$10.5 million to 11.5 million.
- The third quarter 2022 improvements in net revenue, Twirla demand, and Twirla sales reflect a significant increase in sales in the non-retail channel through the Company's collaboration with Afaxys.
 - o Collaboration with Afaxys
 - **Non-retail cycles purchased in the third quarter of 2022 were 6,479, a 361% increase from the 1,404 non-retail cycles dispensed in the second quarter 2022.**
 - The significant non-retail channel growth is the product of the efforts being made by Afaxys to penetrate the Planned Parenthood network.
 - In the third quarter, the Company began to see conversion of large Planned Parenthood accounts in California.

Potential Future Upside from Twirla Business Plan

- The Company expects its business plan to produce further growth in Twirla in the fourth quarter 2022 and 2023.
 - o Enhanced Presence on Connected TV (CTV)
 - Late in the third quarter 2022, the Company relaunched promotion of the Twirla direct-to-consumer commercial on connected TV (CTV) to coincide with the back-to-school months, which have historically been an active time of year for contraception discussions and decisions.
 - The Company plans to run the commercial through the end of 2022 and believes it can raise Twirla awareness, trial and adoption in the fourth quarter 2022.
 - The commercial is targeted to women in the Twirla age demographic of 18-24 years old in key states that have large markets for contraceptives and potentially strong reimbursement coverage for Twirla.
 - o Increased Footprint in Telemedicine
 - In the second quarter 2022, the Company announced its collaboration with female telemedicine leader Nurx that made Twirla an available option to Nurx patients.
 - The launch of the collaboration is occurring in the fourth quarter 2022 and the Company expects to begin to see the impact of Nurx in the retail channel in 2023.
 - Additionally, the Company and Nurx are planning to roll out a shared initiative designed to raise awareness amongst the Nurx contraception patient network of more than 1 million patients.
 - o Potential for Greater Volume Growth
 - After achieving non-retail channel growth of 361% in the third quarter 2022, the Company believes it can continue momentum in the fourth quarter 2022 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.
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Third Quarter 2022 Financial Results

- **Net revenue:** In the third quarter 2022, the Company realized net product sales revenue of \$3.0 million, an increase of 131% as compared to the third quarter 2021 revenue of \$1.3 million.
 - **Cost of product revenues:** Cost of product revenues totaled \$1.4 million and consisted of direct and indirect costs related to the manufacturing of Twirla sold, compared to \$2.7 million for the third quarter 2021 – a decrease of 47%. The decrease reflects the elimination of an inventory obsolescence reserve, which the Company established in the third quarter of 2021.
 - **Total GAAP operating expenses:** Total GAAP operating expenses were \$20.3 million for the quarter ended September 30, 2022, compared to \$14.4 million for the comparable period in 2021 – an increase of 41%. The GAAP operating expenses for the third quarter 2022 represent an increase of 80% from the \$11.3 million of GAAP operating expenses reported for the second quarter 2022.
 - **Total Non-GAAP operating expenses:** Total non-GAAP operating expenses were \$9.2 million for the quarter ended September 30, 2022, compared to \$14.4 million for the comparable period in 2021 – a decrease of 36%. The non-GAAP operating expenses for the third quarter decreased 19% from the \$11.3 million of non-GAAP operating expenses reported for the second quarter 2022. A reconciliation of non-GAAP to GAAP operating expenses is provided in the tables accompanying this press release.
 - **Cash:** As of September 30, 2022, the Company had \$6.1 million of cash, compared to \$13.0 million of cash and cash equivalents as of the end of the second quarter 2022.
 - **Net loss:** Net loss was \$19.7 million, or \$0.53 per share, for the quarter ended September 30, 2022, compared to a net loss of \$16.8 million, or \$7.20 per share, for the comparable period in 2021. The Company incurred a one-time, non-cash operating expense charge of \$11.1 million in the third quarter of 2022 related to the transfer of equipment ownership to Corium, which is reflected in the net loss for the third quarter of 2022.
 - **Shares Outstanding:** As of September 30, 2022, Agile had 39,026,823 shares issued and 36,997,836 weighted average shares of common stock outstanding.
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Conference Call and Webcast

Date	Monday, November 7, 2022
Time	4:30 p.m. ET
Webcast (live and archived)	Events & Presentations
Registration Link	https://edge.media-server.com/mmc/p/32vq9hho

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, 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 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 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 believe that the presentation of non-GAAP operating expenses 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 this non-GAAP financial measure is 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 non-GAAP operating expenses provides meaningful supplemental information regarding our performance; however, we urge investors to review the reconciliation of this financial measures to the comparable GAAP financial measure included in the accompanying table, 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 the fourth quarter of 2022 and 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 connected TV (CTV) campaign and its ability to promote growth, our prospects for future financing arrangements, our expected operating expenses for the fourth quarter of 2022, 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 effects of the ongoing 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 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

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,145	\$ 19,143
Accounts receivable, net	3,711	1,533
Inventory, net	1,797	966
Prepaid expenses and other current assets	3,834	2,283
Total current assets	15,487	23,925
Property and equipment, net	203	12,447
Right of use asset	761	949
Other non-current assets	2,012	2,012
Total assets	\$ 18,463	\$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	\$ 1,318	\$ 16,833
Accounts payable	4,906	8,707
Accrued expenses	5,152	3,563
Lease liability, current portion	277	175
Total current liabilities	11,653	29,278
Lease liabilities, long-term	550	784
Long-term debt	—	—
Total liabilities	12,203	30,062
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, \$.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at September 30, 2022 and no shares issued and outstanding at December 31, 2021	—	—
Common stock, \$.0001 par value, 300,000,000 shares authorized, 39,026,823 and 3,034,901 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	4	—
Additional paid-in capital	437,027	396,388
Accumulated deficit	(430,771)	(387,117)
Total stockholders' equity	6,340	9,271
Total liabilities and stockholders' equity	\$ 18,463	\$ 39,333

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

	Three Months Ended September 30,	
	2022	2021
Revenues, net	\$ 3,002	\$ 1,287
Cost of product revenues	1,425	2,711
Gross profit (loss)	<u>1,577</u>	<u>(1,424)</u>
Operating expenses:		
Research and development	\$ 788	\$ 1,593
Selling and marketing	5,560	9,386
General and administrative	2,815	3,371
Loss on disposition of assets	11,122	—
Total operating expenses	<u>20,285</u>	<u>14,350</u>
Loss from operations	<u>(18,708)</u>	<u>(15,774)</u>
Other income (expense)		
Interest income	46	1
Interest expense	(1,004)	(999)
Total other income (expense), net	<u>(958)</u>	<u>(998)</u>
Loss before benefit from income taxes	<u>(19,666)</u>	<u>(16,772)</u>
Benefit from income taxes	—	—
Net loss	<u>\$ (19,666)</u>	<u>\$ (16,772)</u>
Net loss per share (basic and diluted)	<u>\$ (0.53)</u>	<u>\$ 7.20</u>
Weighted-average common shares (basic and diluted)	<u>36,997,836</u>	<u>2,343,930</u>
Comprehensive loss:		
Net loss	\$ (19,666)	\$ (16,772)
Other comprehensive income:		
Unrealized loss on marketable securities	—	—
Comprehensive loss	<u>\$ (19,666)</u>	<u>\$ (16,772)</u>

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

	Three Months Ended			Nine Months Ended September 30,	
	Q3 2022	Q2 2022	Q3 2021	2022	2021
GAAP Operating expenses	\$ 20,285	\$ 11,293	\$ 14,350	\$ 47,383	\$ 46,217
Non-GAAP adjustment: Loss on disposition of assets	\$ 11,122	—	—	\$ 11,122	—
Non-GAAP operating expenses	\$ 9,163	\$ 11,293	\$ 14,350	\$ 36,261	\$ 46,217
