

**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**

August 11, 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 August 11, 2022, the Company issued a press release announcing its financial results for the three months ended June 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 August 11, 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: August 11, 2022

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

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

Second Consecutive Quarter of Increase in Twirla Demand and Decrease in Company Operating Expenses

Cash on Hand Expected to Fund Operations Through 2022

Company Announces Twirla® Product Supply Agreement with Nurx

Management to Host Conference Call Today, Thursday, August 11, 2022 at 4:30 p.m. ET

PRINCETON, N.J., August 11, 2022 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended June 30, 2022 and provided a corporate update.

“Our goals as a company are to grow our Twirla brand and become cash flow positive. We believe we took important steps towards achieving these goals in the second quarter by once again increasing Twirla demand and revenue while significantly decreasing our operating expenses,” said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. “We plan to drive further growth in the second half of 2022 by executing on previously disclosed components of our business plan like the Afaxys partnership and connected TV campaign, while also exploring and implementing new initiatives like the product supply agreement we are announcing with Nurx, Thirty Madison’s Reproductive Health Brand.”

Second Quarter and Recent Corporate Updates

- *Double Digit Growth in Twirla Demand*
 - o Twirla experienced another quarter of double-digit demand growth. From the end of the first quarter 2022 to the end of the second quarter 2022:
 - Total cycles dispensed grew 27%
 - Retail cycles dispensed grew 22%
 - Non-retail cycles dispensed grew 189%
 - *Significant Reduction in Quarterly Operating Expenses*
 - o Operating expenses for the second quarter 2022 were \$11.3 million – which is below the previously guided range of \$11.5 million to \$12.5 million.
 - o The Company achieved a 28% decrease in quarterly operating expenses compared to operating expenses reported for the first quarter 2022, which were \$15.8 million.
 - o For the second half of 2022, the Company expects quarterly operating expenses to be generally in line with operating expenses reported for the second quarter 2022.
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- The Company believes its existing initiatives and partnerships are contributing to continued growth momentum for Twirla. As of early July 2022, Twirla total cycles dispensed year to date have surpassed the 33,739 total Twirla cycles dispensed in all of 2021.
 - o Partnership with Afaxys
 - The second quarter 2022 growth in the non-retail channel is primarily attributable to the efforts of Afaxys.
 - Non-retail cycles dispensed in the second quarter of 2022 were 1,404; up from the 485 non-retail cycles dispensed in the first quarter 2022.
 - In January 2022, the Company launched a partnership with Afaxys, through their group purchasing organization (GPO), which primarily provides services to the non-retail channel, and a co-promotion program for Twirla with Afaxys Pharma, which has potential access to over 25,000 accounts, including college and university student health centers and Planned Parenthoods.
 - The Company believes there is additional potential for Twirla volume growth in this channel based on the reach of the Afaxys customer network.
 - o Enhanced Presence on Connected TV (CTV)
 - The Company is targeting promotion of the Twirla direct-to-consumer commercial on CTV during the back-to-school months, which have historically been an active time of year for contraception discussions and decisions.
 - In April 2022, the Company launched its first CTV advertisement, focusing on women in the targeted Twirla age demographic of 18-24 years in states that have large markets for contraceptives and potentially strong reimbursement coverage for Twirla.
 - The initial run of the commercial garnered positive results that the Company believes helped raise awareness, trial, and adoption of Twirla.
 - Nurx Product Supply Agreement
 - o In August 2022, the Company signed a product supply agreement which will make Twirla available in the coming months to patients on Nurx, Thirty Madison's Reproductive Health Brand
 - o Nurx is a leader in female-focused telehealth amongst the Twirla target audience and offers patients access to its telehealth platform and expert medical providers that have prescribed contraception to more than 1 million patients.
 - o The Company believes that the Nurx platform will provide an opportunity for more patients to learn about, and potentially access, Twirla.
 - Restructured Agreements
 - o On July 25, 2022, the Company entered into amendments of its Manufacturing and Commercialization Agreement (the "Corium Agreement") with Corium, Inc. ("Corium"), and its Credit Agreement and Guarantee ("Perceptive Credit Agreement") with Perceptive Credit Holdings III, LP ("Perceptive"). The amendment to the Corium Agreement is designed to restructure the minimums applicable to the purchase of manufactured Twirla and other services provided by Corium, transfer equipment ownership to Corium to support the manufacture of Twirla and extend the term of the Corium Agreement. The amendment to the Perceptive Credit Agreement waived the Company's obligations to comply with certain financial covenants through the end of 2022 and released the Company's manufacturing equipment to allow for the restructuring of the Corium Agreement in exchange for an additional pre-payment of \$7 million in principal.
 - Company Financing Activities
 - o In the second quarter 2022, the Company raised net proceeds of approximately \$12.2
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million through its at the market offering (“ATM”), and \$22.2 million in an upsized public offering in July 2022. The Company now believes it has sufficient cash on hand to fund its operations through the end of 2022.

- o The Company reduced the outstanding principal amount owed to Perceptive to \$3 million by using the proceeds from the ATM. The Company paid \$5 million to Perceptive during the second quarter 2022 in connection with the fourth amendment to the Perceptive Credit Agreement. In July 2022, the Company made an additional pre-payment of \$7 million in connection with the fifth amendment to Perceptive Credit Agreement.

Second Quarter 2022 Financial Results

- **Net revenue:** In the second quarter 2022, the Company realized net product sales revenue of \$2.1 million, an increase of 75% as compared to the second quarter 2021 revenue of \$1.2 million.
 - **Cost of product revenues:** Cost of product revenues totaled \$2.2 million and consisted of direct and indirect costs related to the manufacturing of Twirla sold, including third-party manufacturing costs, packaging services, freight, and allocation of overhead costs that are primarily fixed such as depreciation, salaries and benefits, and insurance. Additional costs incurred during the second quarter include \$0.7 million of supplemental payments as agreed to under the amended Corium Agreement.
 - **Total operating expenses:** Total operating expenses were \$11.3 million for the quarter ended June 30, 2022, compared to \$16.7 million for the comparable period in 2021. The reduction in OPEX was primarily attributable to optimization of the Twirla sales force to better focus on the most productive territories with high volume and favorable third-party reimbursement as well as the reduction of expenses across all general and administrative and operating areas.
 - **Cash:** As of June 30, 2022, the Company had \$13.0 million of cash, compared to \$3.7 million of cash and cash equivalents as of the end of the first quarter 2022.
 - **Net loss:** Net loss was \$12.2 million, or \$2.71 per share, for the quarter ended June 30, 2022, compared to a net loss of \$17.6 million, or \$8.00 per share, for the comparable period in 2021.
 - **Shares Outstanding:** As of June 30, 2022, Agile had 12,356,357 shares issued and 4,510,219 weighted average shares of common stock outstanding.
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Conference Call and Webcast

Date	Thursday, August 11, 2022
Time	4:30 p.m. ET
Webcast (live and archived)	Events & Presentations
Dial-in numbers	(888) 330-2454 (U.S. toll-free) or (240) 789-2714
Conference ID	7871426

Investors interested in listening to the conference call may do so by dialing (888) 330-2454 for domestic callers or (240) 789-2714 for international callers. The Conference ID is 7871426. A live webcast will be available in the Events and Presentations section of the Investor Relations page at <https://ir.agiletherapeutics.com/events-and-presentations/>, or by [clicking here](#).

Please log in approximately 10 minutes prior to the scheduled start time. The archived webcast will be available in the Events and Presentations section of the company's website.

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 June 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.

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, 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 future plans with respect to our existing debt financing from Perceptive Advisors, our prospects for future financing arrangements, and our operating expenses, 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

mriley@agiletherapeutics.com

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,027	\$ 19,143
Accounts receivable, net	2,087	1,533
Inventory, net	2,340	966
Prepaid expenses and other current assets	1,016	2,283
Total current assets	18,470	23,925
Property and equipment, net	11,524	12,447
Right of use asset	825	949
Other non-current assets	2,012	2,012
Total assets	\$ 32,831	\$ 39,333
Liabilities and stockholders' equity		
Current liabilities:		
Long-term debt, current portion	\$ 12,630	\$ 16,833
Accounts payable	12,036	8,707
Accrued expenses	3,877	3,563
Lease liability, current portion	239	175
Total current liabilities	28,782	29,278
Lease liabilities, long-term	630	784
Long-term debt	—	—
Total liabilities	29,412	30,062
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.0001 par value, 10,000,000 shares authorized, 4,850 issued and no shares outstanding at June 30, 2022 and no shares issued and outstanding at December 31, 2021	—	—
Common stock, \$.0001 par value, 300,000,000 shares authorized, 12,360,157 and 3,034,901 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	—
Additional paid-in capital	414,523	396,388
Accumulated deficit	(411,105)	(387,117)
Total stockholders' equity	3,419	9,271
Total liabilities and stockholders' equity	\$ 32,831	\$ 39,333

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

	Three Months Ended June 30,	
	2022	2021
Revenues, net	\$ 2,126	\$ 1,185
Cost of product revenues	2,231	1,145
Gross profit (loss)	<u>(105)</u>	<u>40</u>
Operating expenses:		
Research and development	\$ 856	\$ 862
Selling and marketing	7,411	11,977
General and administrative	3,026	3,852
Total operating expenses	<u>11,293</u>	<u>16,691</u>
Loss from operations	<u>(11,398)</u>	<u>(16,651)</u>
Other income (expense)		
Interest income	2	7
Interest expense	(823)	(993)
Total other income (expense), net	<u>(821)</u>	<u>(986)</u>
Loss before benefit from income taxes	(12,219)	(17,637)
Benefit from income taxes	—	—
Net loss	<u>\$ (12,219)</u>	<u>\$ (17,637)</u>
Net loss per share (basic and diluted)	<u>\$ (2.71)</u>	<u>\$ (8.00)</u>
Weighted-average common shares (basic and diluted)	<u>4,510,219</u>	<u>2,217,349</u>
Comprehensive loss:		
Net loss	\$ (12,219)	\$ (17,637)
Other comprehensive income:		
Unrealized loss on marketable securities	—	—
Comprehensive loss	<u>\$ (12,219)</u>	<u>\$ (17,637)</u>