

**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**

July 26, 2021

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.)

101 Poor Farm Road
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 July 26, 2021, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal quarter ended June 30, 2021 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 July 26, 2021.

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: July 26, 2021

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

AGILE THERAPEUTICS REPORTS SECOND QUARTER 2021 FINANCIAL RESULTS

Total Prescriptions (TRx) Grew 171% in Second Quarter

Prescribers, New Prescriptions and Refill Rates Continue to Grow in Second Quarter

Company Continues to Progress on Expanding Access to Twirla

Management to Host Conference Call Today, Monday, July 26, 2021 at 4:30 p.m. EDT

PRINCETON, N.J., July 26, 2021 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended June 30, 2021 and provided a corporate update.

“The theme of Agile’s 2021 second quarter is growth. We believe we have the building blocks in place for continued growth and we remain on track to achieve our near-term goal of establishing Twirla in the \$4.1B U.S. hormonal contraceptive market,” said Chairman and Chief Executive Officer Al Altomari. “We have an approved product that is growing in all major prescription performance areas and we believe we are only scratching the surface as we unleash more direct-to-consumer advertising and further develop the channels that provide women access to Twirla.”

Recent Corporate Developments and Second Quarter 2021 Results:***Twirla Performance and Updates***

- During the second quarter 2021, total prescriptions were 5,027, representing an increase of 171% from the end of the first quarter. New prescriptions were 2,857 and grew by 103% over the same period. The growth was driven by an increase in the number of prescribers, which as of June 30, 2021 was more than 2,087 healthcare providers (HCPs), and growing refill rates. As of June 30, 2021, 2,033 prescriptions dispensed at pharmacies were refills, which represented an increase of 355% during the second quarter. The Company also saw an increase in the number of total prescriptions by prescriber.
- Twirla is now available to Medicaid patients in approximately 75% of states either through traditional Medicaid and/or managed Medicaid. With these new additions, Twirla now has coverage in approximately 50% of the total Medicaid transdermal TRx market with no restrictions. Overall, Twirla has access in approximately 55% of the commercial and government CHC market based on claims.
- In addition to progress on Medicaid and Managed Care access, the Company also saw expanded access through state clinics, where there was significant non-retail prescription volume in the second quarter.

Marketing Campaign Updates

- The Company increased its incremental branded consumer marketing investment quarter over quarter in the second quarter, and Twirla's advertising presence on dating apps such as Tinder and OK Cupid exceeded expectations in less than a month.
- The Company believes that as more women in the target audience gain exposure to Twirla through branded advertising efforts, Twirla prescriptions will continue to grow.

Second Quarter 2021 Financial Results

- **Net revenue:** The Company delivered \$1.2 million in net product sales revenue in the second quarter.
- **Cost of product revenues:** The cost of product revenues for the quarter ended June 30, 2021 was \$1.1 million which included direct and indirect expenses supporting our manufacturing and distribution efforts, including personnel costs and approximately \$500,000 of non-cash depreciation expense. The Company expects these relatively fixed costs to become less significant as a percentage of sales with anticipated volume increases. Until May of 2021, the Company was selling units from validation batches that had no associated product cost as the cost had been previously expensed. Approximately 76% of the units sold in the second quarter had associated product cost. All future sales of product will have an associated product cost.
- **Total operating expenses:** Total operating expenses were \$16.7 million for the quarter ended June 30, 2021, compared to \$10.0 million for the comparable period in 2020. The increase in year-over-year expenses mostly reflected higher selling and marketing expenses, including our contract sales force expenses and brand-building expenses.
- **Research and development (R&D) expenses:** R&D expenses were approximately \$0.9 million for the quarter ended June 30, 2021, compared to \$3.7 million for the comparable period in 2020. The decrease in period-over-period R&D expenses was primarily attributable to the absence of 2020 pre-validation manufacturing costs for commercial manufacturing of Twirla by Corium, the Company's contract manufacturer.
- **Selling and marketing expenses:** Selling and marketing expenses were \$11.7 million for the quarter ended June 30, 2021, compared to \$3.2 million for the comparable period in 2020. The increase in period-over-period selling and marketing expenses was due to higher costs associated with activities for Twirla, including brand building and advocacy, and development of the Company's contract sales force.
- **General and administrative (G&A) expenses:** G&A expenses were \$4.1 million for the quarter ended June 30, 2021, compared to \$3.2 million for the comparable period in 2020. The increase in year-over-year G&A expenses reflected higher personnel costs and higher professional fees.
- **Net loss:** Net loss was \$17.6 million, or \$0.20 per share, for the quarter ended June 30, 2021, compared to a net loss of \$10.8 million, or \$0.12 per share, for the comparable period in 2020.



- **Cash, cash equivalents and marketable securities:** As of June 30, 2021, Agile had \$31.1 million of cash, cash equivalents and marketable securities, compared to \$54.5 million as of December 31, 2020.
- **Shares Outstanding:** As of June 30, 2021, Agile had 92,928,205 shares of common stock outstanding.

Financial Update

- Agile has \$25 million of capital potentially available through its loan facility with Perceptive Advisors, including a tranche of \$15 million in 2021, and a tranche of \$10 million, which will be available through June 2022, both contingent on achieving a pre-determined revenue target.
- Additionally, the Company has the potential to access additional capital through its existing at-the-market arrangement, under which Agile may sell up to an aggregate of \$50 million in gross proceeds through the sale of shares of common stock.

Conference Call and Webcast

Date	Monday, July 26, 2021
Time	4:30 p.m. EDT
Webcast (live and archived)	Events & Presentations
Dial-in numbers	(833) 979-2857 (U.S. toll-free) or (236) 714-2948
Conference ID	1732729

Investors interested in listening to the conference call may do so by dialing (833) 979-2857 for domestic callers or (236) 714-2948 for international callers. 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 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 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 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) 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.

Forward-Looking Statement

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 results of operations, revenues, financial condition, liquidity, prospects, growth and strategies, the expected benefits of our marketing and sales distribution strategies, including the use of samples to grow prescriptions, current and future Medicare coverage for Twirla, the development of our other potential product candidates, the length of time that we will be able to continue to fund our operating expenses and capital expenditures and our expected financing needs and sources of financing, including our debt financing from Perceptive Advisors. 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, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize Twirla, the accuracy of our estimates of the potential market and the market demand for Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, our strategy, business plans and focus, the effects of the COVID-19 pandemic on our operations and the operations of third parties we rely upon as well as on our potential customer base, our ability to meet or exceed the revenue thresholds necessary to permit us to access the remaining amounts available under our existing debt financing from Perceptive Advisors 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,118	\$ 14,463
Marketable securities	4,999	40,008
Accounts receivable, net	1,167	865
Inventory	3,462	—
Prepaid expenses and other current assets	1,202	1,449
Total current assets	36,948	56,785
Property and equipment, net	13,363	14,243
Right of use asset	72	138
Other non-current assets	1,896	1,896
Total assets	\$ 52,279	\$ 73,062
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,410	\$ 3,867
Accrued expenses	5,153	3,348
Lease liability, current portion	72	138
Total current liabilities	11,635	7,353
Long-term debt	16,035	16,381
Total liabilities	27,670	23,734
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 92,928,205 and 87,563,753 issued and outstanding at June 30, 2021 and December 31, 2020, respectively	9	9
Additional paid-in capital	371,588	361,539
Accumulated other comprehensive income	—	3
Accumulated deficit	(346,988)	(312,223)
Total stockholders' equity	24,609	49,328
Total liabilities and stockholders' equity	\$ 52,279	\$ 73,062



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues, net	\$ 1,185	\$ —	\$ 1,301	\$ —
Cost of product revenues	1,145	—	2,306	—
Gross profit (loss)	40	—	(1,005)	—
Operating expenses:				
Research and development	\$ 862	\$ 3,661	\$ 2,975	\$ 6,825
Selling and marketing	11,714	3,150	20,877	4,892
General and administrative	4,115	3,228	8,016	5,939
Total operating expenses	16,691	10,039	31,868	17,656
Loss from operations	(16,651)	(10,039)	(32,873)	(17,656)
Other income (expense)				
Interest income	7	115	23	247
Interest expense	(993)	(902)	(1,915)	(1,300)
Total other income (expense), net	(986)	(787)	(1,892)	(1,053)
Loss before benefit from income taxes	(17,637)	(10,826)	(34,765)	(18,709)
Benefit from income taxes	—	—	—	—
Net loss	\$ (17,637)	\$ (10,826)	\$ (34,765)	\$ (18,709)
Net loss per share (basic and diluted)	\$ (0.20)	\$ (0.12)	\$ (0.39)	\$ (0.23)
Weighted-average common shares (basic and diluted)	88,693,968	87,221,441	88,162,929	81,936,815