

**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**

May 4, 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 May 4, 2021, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal quarter ended March 31, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 4, 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: May 4, 2021

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer



AGILE THERAPEUTICS REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS

Prescription Growth Reflects Increasing Demand for Twirla

Base of Prescribers Continues to Grow in First Quarter 2021

Growing Distribution Network and Marketing Efforts Expected to Drive Healthcare Provider and Consumer Engagement

PRINCETON, N.J., May 4, 2021 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2021 and provided a corporate update.

“In December 2020, we began our initial commercial shipments of Twirla® to wholesalers, who have been working down their inventories during the first quarter of 2021. As wholesalers complete the inventory work-down, we expect product revenue from wholesalers will more closely reflect script demand growth for Twirla at the retail level. We are encouraged by recent trends, which we believe reflect our anticipated momentum and show steady, increasing demand for our product and a growing base of prescribers.” said Chairman and Chief Executive Officer, Al Altomari. “We continue to be optimistic about Twirla’s trajectory and are encouraged by the response to our product, the first and only weekly contraceptive patch that delivers a low dose of estrogen.”

Recent Corporate Developments and First Quarter 2021 Results:

Twirla Performance and Updates

- During the first quarter 2021, total prescriptions were 1,853. The growth was driven by an increase in the number of prescribers, which as of March 31, 2021 was more than 900 HCPs, and growing refill rates. As of March 31, 2021, 447 of prescriptions dispensed at pharmacies were refills. The Company also saw an increase in the number of total prescriptions by prescriber.
- The Company believes its momentum in prescriptions reflects underlying demand for Twirla and is supported by steady growth in the first quarter, which has continued into the early second quarter.
- The Company continues to focus on expanding access and reimbursement coverage for Twirla across managed care and government health insurance plans. During the first quarter 2021, the Company made progress in obtaining Medicaid coverage for Twirla. Currently, Twirla is covered with no prior authorization in 20 states with expected coverage pending in Texas in May 2021. The Medicaid market represents a large number of combined hormonal contraceptive (“CHC”) users; Medicaid volumes for oral CHC total prescriptions in 2020 were nearly eight million.

- In February 2021, the Company entered into a specialty distribution agreement with Sterling Specialty Pharmacy (“Sterling”). The Company believes that the relationship with Sterling will facilitate increased access to Twirla based on early results, which have been productive in increasing uptake of Twirla. Agile continues to explore the potential to expand its distribution network through other channels that can support growth of Twirla demand including telemedicine.

Marketing Campaign Updates

- The Company continues to support *I’m So Done*, an education and empowerment unbranded awareness campaign that encourages women to think about their current contraceptive method and decision-making journey. The Company has seen increased activity on its website and various applications, including Tik Tok.
- Beginning in the second quarter the Company plans to shift a significant portion of its investment in marketing to its branded campaign. The Company plans to focus its branded campaign efforts on driving awareness and trial of Twirla, with a goal of meeting women throughout their everyday routine with a targeted digital strategy.
 - o Ongoing efforts include a multi-channel creative campaign that positions Twirla as the first and only weekly contraceptive patch that delivers a low dose of estrogen.
 - o The Company plans to expand its digital reach to other applications including Tinder and OkCupid, as well as Spotify. These three applications reach millions of U.S. women between the ages of 18 and 34 on a monthly basis.

First Quarter 2021 Financial Results

- **Net revenue:** The Company delivered \$116,000 in net product sales revenue in the first quarter, as wholesalers worked down their inventory levels after the initial stocking of Twirla in the prior quarter.
- **Cost of product revenues:** The cost of product revenues for the quarter ended March 31, 2021 was \$1.2 million which included 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. There was no direct cost of product revenue during the three months ended March 31, 2021, as all product sold consisted of validation inventory which was previously expensed as research and development expense in the fourth quarter of 2020. The Company expects all validation inventory with a carrying value of zero to be utilized in 2021.
- **Total operating expenses:** Total operating expenses were \$15.2 million for the quarter ended March 31, 2021, compared to \$7.6 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. The Company anticipates its second quarter 2021 total operating expenses will be approximately \$18 to \$20 million reflecting increased commercial costs from product samples and spending on branded marketing.

- **Research and development (R&D) expenses:** R&D expenses were approximately \$2.1 million for the quarter ended March 31, 2021, compared to \$3.2 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, offset in part by higher clinical development and personnel-related expenses.
- **Selling and marketing expenses:** Selling and marketing expenses were \$9.2 million for the quarter ended March 31, 2021, compared to \$1.7 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 \$3.9 million for the quarter ended March 31, 2021, compared to \$2.7 million for the comparable period in 2020. The increase in year-over-year G&A expenses reflected higher personnel costs and professional fees in preparation for product launch and commercial activities, as well as an increase in stock compensation expense.
- **Net loss:** Net loss was \$17.1 million, or \$0.20 per share, for the quarter ended March 31, 2021, compared to a net loss of \$7.9 million, or \$0.10 per share, for the comparable period in 2020.
- **Cash, cash equivalents and marketable securities:** As of March 31, 2021, Agile had \$40.1 million of cash, cash equivalents and marketable securities, compared to \$54.5 million as of December 31, 2020.
- **Shares Outstanding:** As of March 31, 2021, Agile had 88,263,741 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

Agile Therapeutics will host a conference call and webcast to discuss financial results for the first quarter ended March 31, 2021, today at 4:30 pm ET. Investors interested in listening to the conference call may do so by dialing (866) 324-3683 for domestic callers or (509) 844-0959 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 forward-looking 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.

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 amount 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

mriley@agiletherapeutics.com



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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,464	\$ 14,463
Marketable securities	23,647	40,008
Accounts receivable, net	322	865
Inventory	1,590	—
Prepaid expenses and other current assets	1,651	1,449
Total current assets	43,674	56,785
Property and equipment, net	13,801	14,243
Right of use asset	106	138
Other non-current assets	1,896	1,896
Total assets	\$ 59,477	\$ 73,062
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,944	\$ 3,867
Accrued expenses	2,737	3,348
Lease liability, current portion	106	138
Total current liabilities	8,787	7,353
Long-term debt	15,636	16,381
Total liabilities	24,423	23,734
Commitments and contingencies		
Stockholders' equity		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 88,263,741 and 87,563,753 issued and outstanding at March 31, 2021 and December 31, 2020, respectively	9	9
Additional paid-in capital	364,396	361,539
Accumulated other comprehensive income	—	3
Accumulated deficit	(329,351)	(312,223)
Total stockholders' equity	35,054	49,328
Total liabilities and stockholders' equity	\$ 59,477	\$ 73,062



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

	Three Months Ended	
	March 31,	
	2021	2020
Revenues, net	\$ 116	\$ —
Cost of product revenues	1,161	—
Gross profit	<u>(1,045)</u>	<u>—</u>
Operating expenses:		
Research and development	\$ 2,113	\$ 3,164
Selling and marketing	9,163	1,742
General and administrative	3,901	2,711
Total operating expenses	<u>15,177</u>	<u>7,617</u>
Loss from operations	<u>(16,222)</u>	<u>(7,617)</u>
Other income (expense)		
Interest income	16	132
Interest expense	(922)	(398)
Total other income (expense), net	<u>(906)</u>	<u>(266)</u>
Loss before benefit from income taxes	(17,128)	(7,883)
Benefit from income taxes	—	—
Net loss	<u>\$ (17,128)</u>	<u>\$ (7,883)</u>
Net loss per share (basic and diluted)	<u>\$ (0.20)</u>	<u>\$ (0.10)</u>
Weighted-average common shares (basic and diluted)	<u>87,625,990</u>	<u>76,652,190</u>