

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 2, 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 November 2, 2021, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal quarter ended September 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 November 2, 2021.
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 2, 2021

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

AGILE THERAPEUTICS REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS

Prescription Demand Growth Continues in the Third Quarter 2021 with a 61% Increase in Twirla Cycles Dispensed

Twirla Refill Rates Continue to Grow by 86% in Third Quarter 2021

Company Advances Programs Focused on Increasing Demand for Twirla

Management to Host Conference Call Today, Tuesday, November 2, 2021 at 4:30 p.m. EDT

PRINCETON, N.J., November 2, 2021 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended September 30, 2021 and provided a corporate update.

"We are encouraged by solid double-digit growth in prescription demand as measured by cycles dispensed. We are excited that the quarterly prescription growth came from both new prescriptions and refills," said Chairman and Chief Executive Officer Al Altomari. "Our goal is to continue to accelerate growth for the Twirla brand and reduce our time to profitability. We believe we have the awareness and access programs in place to execute on our plans and intend to make meaningful investments in marketing to help increase demand."

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

- During the third quarter 2021, total cycles dispensed were 9,747, representing an increase of 61% from the end of the second quarter. Total prescriptions in the third quarter 2021 were 7,374, representing an increase of 47% from the end of the second quarter. New prescriptions were 3,584 and grew by 25% over the same period. Prescription growth was driven by an increase in the number of prescribers, which as of September 30, 2021 was approximately 3,394 healthcare providers (HCPs), and growing refill rates. As of September 30, 2021, 3,790 prescriptions dispensed at pharmacies were refills, which represented an increase of 86% during the third quarter. The Company also saw an increase in the number of total prescriptions by prescriber.
- In the third quarter 2021, the Company announced a partnership with Pandia Health, a telehealth service provider, which is now active. Pandia offers an additional point of access for Twirla in a fast-growing channel and represents the first telehealth alliance for Agile and Twirla.
- Medi-Cal, the California Medicaid program, placed Twirla on the preferred drug formulary list effective October 1, 2021. This secured a preferred position for Twirla on the formulary for Medi-Cal and related programs which provide health care to approximately 15 million beneficiaries. This is significant for Twirla because Medi-Cal is the largest Medicaid program in

the U.S., and the Company believes roughly one-third of the existing contraceptive patch market comes from Medicaid.

- The Company recently activated a branded influencer program on Instagram to increase awareness of Twirla as a birth control option and encourage women in the target market to engage in open conversation about the product.
- Additionally, the Company announced that Twirla is the first prescription birth control brand to launch podcast advertisements on Spotify. Twirla is also the first birth control brand to run custom content across BuzzFeed, leveraging their social handles across Facebook, Instagram, and Snapchat.
- On October 7, the Company appointed Josephine Torrente as a Class II director to the Company's Board of Directors. Ms. Torrente is a regulatory strategist with extensive experience guiding new drug therapies through the FDA approval process. She also has extensive experience helping companies and investors evaluate pipelines and acquisitions. The Company believes her combined experience will contribute to its efforts to grow as a commercial company.

Third Quarter 2021 Financial Results

- **Net revenue:** The Company delivered \$1.3 million in net product sales revenue in the third quarter.
- **Cost of product revenues:** The cost of product revenues for the quarter ended September 30, 2021 was \$2.7 million, which included a \$1.4 million reserve for inventory not expected to be sold prior to its shelf-life date and direct and indirect expenses supporting our manufacturing and distribution efforts, including personnel costs and approximately \$500,000 of non-cash depreciation expense.
- **Total operating expenses:** Total operating expenses were \$14.4 million for the quarter ended September 30, 2021, compared to \$14.7 million for the comparable period in 2020. Higher selling and marketing expenses were more than offset by lower research and development expenses. The Company anticipates its quarterly spending for the fourth quarter 2021 will be in the range of \$15 to \$18 million, with increases reflecting commercial spending on product sample batches and branded marketing.
- **Research and development (R&D) expenses:** R&D expenses were approximately \$1.6 million for the quarter ended September 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 \$9.4 million for the quarter ended September 30, 2021, compared to \$7.7 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 \$3.4 million for the quarter ended September 30, 2021, compared to \$3.3 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 \$16.8 million, or \$0.18 per share, for the quarter ended September 30, 2021, compared to a net loss of \$15.5 million, or \$0.18 per share, for the comparable period in 2020.
- **Cash and cash equivalents:** As of September 30, 2021, Agile had \$14.7 million of cash and cash equivalents, compared to \$31.1 million of cash, cash equivalents and marketable securities as of the end of second quarter 2021 and \$54.5 million as of December 31, 2020.
- **Shares Outstanding:** As of September 30, 2021, Agile had 94,729,385 shares of common stock outstanding.

Financial Update

- On October 13, 2021, the Company raised net proceeds of approximately \$21.1 million in a public offering.

Conference Call and Webcast

Date	Tuesday, November 2, 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	9988403

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. The required Conference ID is 9988403. 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 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 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, current and future Medicare coverage for Twirla, and the development of our other potential product candidates. 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,735	\$ 14,463
Marketable securities	—	40,008
Accounts receivable, net	1,309	865
Inventory, net	3,460	—
Prepaid expenses and other current assets	2,258	1,449
Total current assets	21,762	56,785
Property and equipment, net	12,911	14,243
Right of use asset	37	138
Other non-current assets	1,972	1,896
Total assets	\$ 36,682	\$ 73,062
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,632	\$ 3,867
Accrued expenses	3,899	3,348
Lease liability, current portion	37	138
Total current liabilities	9,568	7,353
Long-term debt	16,434	16,381
Total liabilities	26,002	23,734
Commitments and contingencies		
Stockholders' equity		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 94,729,385 and 87,563,753 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	9	9
Additional paid-in capital	374,431	361,539
Accumulated other comprehensive income	—	3
Accumulated deficit	(363,760)	(312,223)
Total stockholders' equity	10,680	49,328
Total liabilities and stockholders' equity	\$ 36,682	\$ 73,062

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues, net	\$ 1,287	\$ —	\$ 2,587	\$ —
Cost of product revenues	2,711	—	5,017	—
Gross profit (loss)	(1,424)	—	(2,430)	—
Operating expenses:				
Research and development	\$ 1,593	\$ 3,663	\$ 4,568	\$ 10,488
Selling and marketing	9,386	7,723	30,263	12,616
General and administrative	3,371	3,270	11,386	9,208
Total operating expenses	14,350	14,656	46,217	32,312
Loss from operations	(15,774)	(14,656)	(48,647)	(32,312)
Other income (expense)				
Interest income	1	37	24	284
Interest expense	(999)	(905)	(2,914)	(2,205)
Total other income (expense), net	(998)	(868)	(2,890)	(1,921)
Loss before benefit from income taxes	(16,772)	(15,524)	(51,537)	(34,233)
Benefit from income taxes	—	—	—	—
Net loss	\$ (16,772)	\$ (15,524)	\$ (51,537)	\$ (34,233)
Net loss per share (basic and diluted)	\$ (0.18)	\$ (0.18)	\$ (0.57)	\$ (0.41)
Weighted-average common shares (basic and diluted)	93,757,215	87,350,505	90,048,183	83,754,550