

**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, 2020

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 August 11, 2020, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2020 and providing an update on the Company’s operations for the same period. 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 August 11, 2020

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, 2020

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer



Agile Therapeutics Reports Second Quarter 2020 Financial Results

Twirla® on Track for Commercial Launch in Fourth Quarter 2020

\$87.2 Million in Cash and Cash Equivalents as of June 30, 2020

Management to Host Conference Call at 4:30 PM ET

PRINCETON, New Jersey, August 11, 2020 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and six months ended June 30, 2020 and provided a corporate update.

“Thanks to the dedication and commitment of the Agile team, we made considerable progress on our objectives and we believe we are on track to launch Twirla in the fourth quarter of 2020. During the second quarter, we transitioned into the final validation phase of manufacturing commercial product. Through Syneos Selling Solutions, our contract sales force partner, we also hired several industry veterans to build out our sales force highlighted by Terry Herring, a recognized leader with more than 30 years of pharmaceutical and healthcare experience, as our new National Sales Leader. We believe our strong financial position and cash balance, combined with our recent achievements, set us up well to commercially launch Twirla and establish Agile in the contraceptive prescription marketplace,” said Al Altomari, Chairman and Chief Executive Officer of Agile.

Second Quarter 2020 and Other Recent Corporate Developments:

COVID-19 Update

- As of today, despite the COVID-19 pandemic, the Company has been able to continue to execute its plans according to planned timelines, including its hiring a sales team, pre-validation and validation of the commercial manufacturing process and its current expectations to ship Twirla to wholesalers. This expectation is subject to change depending on the length, uncertainty or change in market conditions related to the pandemic.

Twirla Commercialization Update

- In the second quarter 2020, the Company completed production of the planned pre-validation batch of Twirla and transitioned to manufacturing validation batches.
 - Presently manufacturing three validation batches that the Company expects will produce commercially-usable product.
 - The Company continues to work with managed care and patient payors to gain market access for Twirla.
 - Through Syneos Selling Solutions, the Company’s contract sales force partner, hired a national sales leader and seven experienced regional sales managers, and is in the process of hiring a target of 73 total territory and telemarketing sales reps.
 - The Company intends to begin shipping product to wholesalers in the fourth quarter of 2020.
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Inclusion into the Russell 3000® and 2000® Indexes

- In June 2020, the Company was added to the Russell 3000 and 2000 Indexes, as part of the Russell Indexes annual reconstitution.

Financial Guidance

- The Company reaffirmed its operating expense guidance for the full year 2020 to be in the range of \$52 million to \$56 million, with general and administrative expenses accounting for approximately 70% of the spending as it builds out its commercial infrastructure. The Company's operating expenses guidance includes \$2.5 million to \$3 million of non-cash stock compensation expense. The Company updated its net revenue guidance in the fourth quarter of 2020, reflecting refined expectations of initial stocking levels, to be in the range of \$1 million to \$2 million.
- Based on the Company's current business plan and ability to launch Twirla, the Company believes that its cash, cash equivalents and marketable securities as of June 30, 2020 will be sufficient to meet its projected operating requirements through the end of 2021. If the COVID-19 pandemic or other factors impact the Company's current business plans or its ability to generate revenue from the launch of Twirla, the Company believes it has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

Second Quarter Financial Results

- **Cash, cash equivalents and marketable securities:** As of June 30, 2020, Agile had \$87.2 million of cash, cash equivalents and marketable securities compared to \$34.5 million of cash and cash equivalents as of December 31, 2019.
- **Research and development (R&D) expenses:** R&D expenses were \$3.7 million for the quarter ended June 30, 2020, compared to \$1.8 million for the comparable period in 2019. The increase in R&D expenses was primarily due to costs to complete manufacturing development, process improvements, and pre-validation work for commercial manufacturing of Twirla by Corium, the Company's contract manufacturer.
- **General and administrative (G&A) expenses:** G&A expenses were \$6.4 million for the quarter ended June 30, 2020, compared to \$1.8 million for the comparable period in 2019. The increase in G&A expenses was primarily due to higher costs associated with our pre-commercialization activities for Twirla, such as brand building, advocacy, market research and consulting. The increase in G&A expenses was also attributable to activities related to building out the commercial organization and included higher salaries and higher professional fees related to recruiting fees and consultants, and an increase in stock compensation expense.
- **Net loss:** Net loss was \$10.8 million, or \$0.12 per share, for the quarter ended June 30, 2020, compared to a net loss of \$3.5 million, or \$0.08 per share, for the comparable period in 2019.
- **Shares Outstanding:** At June 30, 2020, Agile had 87,297,605 shares of common stock outstanding.

Conference Call and Webcast

Agile Therapeutics will host a conference call and webcast to discuss financial results for the second quarter ended June 30, 2020 today at 4:30pm ET. Investors interested in listening to the conference call may do so by dialing (877) 407-2991 for domestic callers or (201) 389-0925 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 to prevent pregnancy. 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 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 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 the market availability of Twirla, our projected cash position, our projected fiscal year 2020 operating expenses and net revenue and the expected timing and structure of our commercialization plan for Twirla. 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, our ability along with our third-party manufacturer, Corium, to complete successfully the scale-up of the commercial manufacturing process for Twirla, the performance and financial condition of Corium or any of its suppliers, 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 successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market 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, 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
mriley@agiletherapeutics.com

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,446	\$ 34,479
Marketable securities	47,789	—
Prepaid expenses	1,527	840
Total current assets	88,762	35,319
Property and equipment, net	14,208	14,044
Right of use and other assets	94	177
Total assets	\$ 103,064	\$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,121	\$ 1,819
Accrued expenses	1,290	1,804
Lease liability, current portion	82	172
Total current liabilities	6,493	3,795
Long-term debt	15,775	—
Total liabilities	22,268	3,795
Commitments and contingencies		
Stockholders' equity		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 87,297,605 and 69,810,305 issued and outstanding at June 30, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	359,856	306,108
Accumulated other comprehensive income	10	—
Accumulated deficit	(279,079)	(260,370)
Total stockholders' equity	80,796	45,745
Total liabilities and stockholders' equity	\$ 103,064	\$ 49,540

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 3,661	\$ 1,779	\$ 6,825	\$ 4,660
General and administrative	6,378	1,768	10,831	3,594
Total operating expenses	10,039	3,547	17,656	8,254
Loss from operations	(10,039)	(3,547)	(17,656)	(8,254)
Other income (expense)				
Interest income	115	63	247	101
Interest expense	(902)	—	(1,300)	—
Total other income (expense), net	(787)	63	(1,053)	101
Loss before benefit from income taxes	(10,826)	(3,484)	(18,709)	(8,153)
Benefit from income taxes	—	—	—	—
Net loss	\$ (10,826)	\$ (3,484)	\$ (18,709)	\$ (8,153)
Net loss per share (basic and diluted)	\$ (0.12)	\$ (0.08)	\$ (0.23)	\$ (0.20)
Weighted-average common shares (basic and diluted)	87,221,441	43,776,549	81,936,815	40,560,259
Comprehensive loss:				
Net loss	\$ (10,826)	\$ (3,484)	\$ (18,709)	\$ (8,153)
Other comprehensive income:				
Unrealized gain on marketable securities	10	—	10	—
Comprehensive loss	\$ (10,816)	\$ (3,484)	\$ (18,699)	\$ (8,153)