

**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 12, 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 November 12, 2020, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 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 November 12, 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: November 12, 2020

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

Agile Therapeutics Reports Third Quarter 2020 Financial Results

Commercial Launch of Twirla® Expected by Year-End 2020

\$71.9 Million in Cash, Cash Equivalents, and Marketable Securities as of September 30, 2020

Management to Host Conference Call today at 4:30 PM ET

PRINCETON, New Jersey, November 12, 2020 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and nine months ended September 30, 2020 and provided a corporate update.

“With our commercial launch of Twirla expected by the end of the year, we remain on track to deliver on our plan. The final validation of our commercial manufacturing process continues to progress as all three of our batches are expected to be released for commercial use in December 2020. By taking steps to build out an experienced sales force, secure major wholesaler agreements and increase market access for Twirla, we believe we are well-prepared to hit the ground running. Having our first FDA-approved product nearing launch marks an exciting time for Agile and we look forward to bringing to the market another choice for women to help fulfill their contraceptive needs,” said Al Altomari, Chairman and Chief Executive Officer of Agile.

Third Quarter 2020 and Other Recent Corporate Developments:

Twirla Commercialization Update

- The Company intends to begin shipping product to wholesalers by year-end 2020.
- Agile remains on track to finalize the validation of its commercial manufacturing process of Twirla.
 - o All three validation batches are expected to be released for commercial use in December 2020.
- The Company continued to build its distribution network by entering into an agreement with a third major U.S. wholesaler.
- The Company continues to build awareness among prescribers and health care providers to gain market access for Twirla.
 - o Product sampling expected to begin at launch.
- Through Syneos Selling Solutions, the Company’s contract sales force partner, Agile completed the hiring of an initial sales team of 73 persons.
 - o The sales force initiated discussions with healthcare providers after it was fully deployed in mid-October.

Strengthened Executive Leadership Team

- In August 2020, the Company appointed Paul Korner, MD, MBA, as Chief Medical Officer. Dr. Korner is a board-certified obstetrician and gynecologist with more than 20 years of pharmaceutical and biotech industry experience, including significant experience within women’s healthcare.

Launched *I’m So Done* – A National Unbranded Campaign

- In September 2020, the Company launched *I’m So Done*, an education and empowerment platform that encourages women to think about their current contraceptive method and decision-making journey.
-

Financial Guidance

- The Company narrowed its operating expense guidance for the full year 2020 to be in the range of \$52 million to \$54 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 \$2.7 million to \$3 million of non-cash stock compensation expense. The Company expects its gross revenue in the fourth quarter of 2020, reflecting expectations of initial stocking of Twirla by wholesalers, to be approximately \$1 million.
- Based on the Company's current business plan and pending launch of Twirla, the Company believes that its cash, cash equivalents and marketable securities as of September 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.

Third Quarter Financial Results

- **Cash, cash equivalents and marketable securities:** As of September 30, 2020, Agile had \$71.9 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 September 30, 2020, compared to \$2.4 million for the comparable period in 2019. The increase in R&D expenses was primarily due to costs to conduct validation work for commercial manufacturing of Twirla by Corium, the Company's contract manufacturer.
- **General and administrative (G&A) expenses:** G&A expenses were \$11.0 million for the quarter ended September 30, 2020, compared to \$2.1 million for the comparable period in 2019. The increase in G&A expenses was primarily due to higher costs associated with the Company's 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 \$15.5 million, or \$0.18 per share, for the quarter ended September 30, 2020, compared to a net loss of \$4.4 million, or \$0.08 per share, for the comparable period in 2019.
- **Shares Outstanding:** As of September 30, 2020, Agile had 87,434,604 shares of common stock outstanding.

Conference Call and Webcast

Agile Therapeutics will host a conference call and webcast to discuss financial results for the third quarter ended September 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 status and timing of the validation of our commercial manufacturing process, market availability of Twirla, our projected cash position, our projected fiscal year 2020 operating expenses and gross 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 & Corporate Communications
mriley@agiletherapeutics.com

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,163	\$ 34,479
Marketable securities	47,742	—
Prepaid expenses	1,414	840
Total current assets	73,319	35,319
Property and equipment, net	14,271	14,044
Right of use asset	31	158
Other non-current assets	1,791	19
Total assets	\$ 89,412	\$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,016	\$ 1,819
Accrued expenses	2,154	1,804
Lease liability, current portion	34	172
Total current liabilities	7,204	3,795
Long-term debt	16,078	—
Total liabilities	23,282	3,795
Commitments and contingencies		
Stockholders' equity		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 87,434,604 and 69,810,305 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	360,713	306,108
Accumulated other comprehensive income	11	—
Accumulated deficit	(294,603)	(260,370)
Total stockholders' equity	66,130	45,745
Total liabilities and stockholders' equity	\$ 89,412	\$ 49,540

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 3,663	\$ 2,361	\$ 10,488	\$ 7,021
General and administrative	10,993	2,138	21,824	5,732
Total operating expenses	14,656	4,499	32,312	12,753
Loss from operations	(14,656)	(4,499)	(32,312)	(12,753)
Other income (expense)				
Interest income	37	67	284	168
Interest expense	(905)	—	(2,205)	—
Total other income (expense), net	(868)	67	(1,921)	168
Loss before benefit from income taxes	(15,524)	(4,432)	(34,233)	(12,585)
Benefit from income taxes	—	—	—	—
Net loss	\$ (15,524)	\$ (4,432)	\$ (34,233)	\$ (12,585)
Net loss per share (basic and diluted)	\$ (0.18)	\$ (0.08)	\$ (0.41)	\$ (0.28)
Weighted-average common shares (basic and diluted)	87,350,505	53,609,511	83,754,550	44,957,809
Comprehensive loss:				
Net loss	\$ (15,524)	\$ (4,432)	\$ (34,233)	\$ (12,585)
Other comprehensive income:				
Unrealized gain on marketable securities	1	—	11	—
Comprehensive loss	\$ (15,523)	\$ (4,432)	\$ (34,222)	\$ (12,585)