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 5, 2020
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(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 5, 2020, Agile Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 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.

Exhibit Number	Description
99.1	Press Release dated May 5, 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: May 5, 2020

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: Chairman and Chief Executive Officer

Agile Therapeutics Reports First Quarter 2020 Financial Results

FDA Approved Twirla® Expected to Reach Wholesalers in the Fourth Quarter of 2020

$93. 9 million in Cash and Cash Equivalents as of March 31, 2020

Management to Host Conference Call at 4:30 PM ET

PRINCETON, New Jersey, May 5, 2020 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2020 and provided a corporate update.

“At the beginning of the COVID-19 pandemic, we took proactive steps by moving all employees to work from home settings for their health and safety, while pursuing business continuity during this pivotal time in the Company’s history,” said Al Altomari, Chairman and Chief Executive Officer of Agile. “Despite a challenging operating environment, we expect our precommercial activities to remain on track to bring Twirla to market in the fourth quarter of 2020. With respect to our manufacturing process, we have completed production of the pre-validation batch and subject to final quality control testing that we expect to be completed soon, we will transition into the final validation phase. We plan to initiate the manufacture of our validation batches at the same time that we expect to build our sales force and commercial infrastructure to facilitate the product launch. By raising more than $68 million in debt and equity financing in recent months, we expect to have the financial runway needed to achieve our next milestone, which is the initial shipment of Twirla, so that we can begin taking a share of the $4.1 billion estimated potential addressable market. It was a transformational quarter for Agile with FDA approval of Twirla, a truly game changing moment that now enables us to focus on commercialization.”

First Quarter 2020 and Other Recent Corporate Developments:

COVID-19 Update

- Agile Therapeutics has taken preventative measures to protect the health and wellbeing of its employees, such as a company-wide mandate to have all employees work from home, in accordance with state and local guidelines. As of today, the Company does not expect a material impact to financial results, its hiring and training of its sales team, pre-validation and validation of the commercial manufacturing process or its current expectations to ship Twirla to wholesalers, however, this expectation is subject to change depending on the length, uncertainty and change in market conditions related to the pandemic.

Twirla® Update

- *Twirla (levonorgestrel and ethynyl estradiol) transdermal system Approved by FDA:* On February 14, 2020, the Company announced that it had received FDA approval for its lead product candidate, Twirla. Twirla is approved for the prevention of pregnancy in women with a BMI <30 kg/m^2 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/m^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2.

- *Twirla Commercialization Plans*: The Company has completed production of the planned manufacturing pre-validation batch of Twirla and subject to completion of the final quality assurance testing, the Company expects to begin manufacture of the validation batches of Twirla® over the next four months. The Company expects these validation batches, if successful, will be available for commercial launch in the fourth quarter of 2020. At the same time, the Company will continue to prepare for the availability of commercial product supply. The Company has initiated work with managed care and patient payors to gain market access for Twirla. In the second quarter of 2020, the Company plans to begin hiring and training an initial sales team, which it estimates to be in the range of 70 to 100 persons. The Company intends to begin to ship product to wholesalers in the fourth quarter of 2020.

Financing Update

- In February 2020, the Company entered into a credit agreement with Perceptive Advisors for a senior secured term loan facility of up to $35 million. A first tranche of $5 million was funded on execution of the credit agreement. A second tranche of $15 million was funded as a result of the approval of Twirla by the FDA. Another $15 million tranche will be available upon the achievement of certain revenue milestones. The Company is permitted to make interest-only payments on the loan until February 2023. In addition, the Company issued Perceptive warrants to purchase 1,400,000 shares of Agile common stock.

- In February 2020, the Company completed a public offering of 17,250,000 shares of common stock at a public offering price of $3.00 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and offering expenses payable by Agile Therapeutics, were approximately $48.4 million.

Financial Guidance

- Moving forward, the Company plans to monitor spending closely. The Company expects operating expenses for the full year 2020 to be in the range of $52.0 million to $56.0 million, with general and administrative expenses accounting for approximately 70% of the spending as it builds out its commercial infrastructure. Net revenue in the fourth quarter of 2020, reflecting the initial launch of Twirla, is expected to be in the range of $4.0 million to $6.0 million. Based on the Company's current business plan and ability to get Twirla launched, the Company believes that its cash and cash equivalents as of March 31, 2020 will be sufficient to meet its projected operating requirements through the end of 2021. If the COVID-19 outbreak or other factors impact the Company's business plan 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.

First Quarter Financial Results

- **Cash and cash equivalents:** As of March 31, 2020, Agile had $93.9 million of cash and cash equivalents 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 $3.2 million for the quarter ended March 31, 2020, compared to $2.9 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, our contract manufacturer. These higher expenses were offset by lower clinical development expenses related to the comparative wear study of Twirla and Xulane, which was initiated and completed in the quarter ended March 31, 2019.

- **General and administrative (G&A) expenses:** G&A expenses were $4.4 million for the quarter ended March 31, 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. We also incurred higher salaries and wages and higher professional fees related to recruiting fees and consultants.

- **Net loss:** Net loss was $7.9 million, or $0.10 per share, for the quarter ended March 31, 2020, compared to a net loss of $4.7 million, or $0.13 per share, for the quarter ended December 31, 2019.

- **Shares Outstanding:** At March 31, 2020, Agile had 87,213,212 shares of common stock outstanding.

Conference Call and Webcast

Agile Therapeutics will host a conference call and webcast to discuss financial results for the first quarter ended March 31, 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 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, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility, 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.

Source: Agile Therapeutics

Contact: Investor Relations -- 609-683-1880

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 93,925	$ 34,479
Prepaid expenses	672	840
Total current assets	94,597	35,319
Property and equipment, net	14,154	14,044
Other assets	136	177
Total assets	$ 108,887	$ 49,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,680	$ 3,623
Lease liability, current portion	128	172
Total current liabilities	2,808	3,795
Long-term debt	15,472	—
Stockholders' equity		
Common stock	9	7
Additional paid-in capital	358,851	306,108
Accumulated deficit	(268,253)	(260,370)
Total stockholders' equity	90,607	45,745
Total liabilities and stockholders' equity	$ 108,887	$ 49,540

Agile Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 3,164	$ 2,881
General and administrative	4,453	1,826
Total operating expenses	7,617	4,707
Loss from operations	(7,617)	(4,707)
Other income (expense)		
Interest income	132	38
Interest expense	(398)	—
Loss before benefit from income taxes	(7,883)	(4,669)
Benefit from income taxes	—	—
Net loss	$ (7,883)	$ (4,669)
Net loss per share - basic and diluted	$ (0.10)	$ (0.13)
Weighted-average shares outstanding –basic and diluted	76,652,190	37,308,232