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

February 20, 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 February 20, 2020, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2019 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 Current Report on Form 8-K (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 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 issued by Agile Therapeutics, Inc. dated February 20, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: February 20, 2020

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

Exhibit 99.1

Agile Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

Current Cash and Cash Equivalents Expected to Meet Projected Operating Requirements through End of 2020

Twirla®, Company's Lead Product Candidate, Receives FDA Approval

Company Plans to Commence Distributing Product to Wholesalers in the Fourth Quarter of 2020

PRINCETON, New Jersey, February 20, 2020 - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three months and year ended December 31, 2019 and provided a corporate update.

Fourth Quarter 2019 and Other Recent Corporate Developments:

Twirla® Update

- *FDA Advisory Committee Meeting Completed:* As previously announced, in October 2019, The Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) of the U.S. Food and Drug Administration (FDA) met to discuss the Company's New Drug Application for Twirla. The BRUDAC voted 14-1, with 1 abstention, that the benefits of Twirla in the prevention of pregnancy outweigh the risks to support approval.

- *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 plans to begin the pre-validation and validation of the commercial manufacturing process in the first half of 2020, manufacture three validation batches of Twirla and complete the validation process in the second half of 2020. At the same time, the Company will prepare for the availability of commercial product supply. In the first quarter of 2020, the Company intends to initiate 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 ship product to wholesalers in the fourth quarter of 2020.

Financing Update

- In November 2019, the Company entered into an at-the market (ATM) agreement, under which the Company was authorized to issue and sell shares of common stock having aggregate sales proceeds of up to $20.0 million from time to time. In the year ended December 31, 2019, the Company issued and sold 10,440,908 shares of common stock under the ATM, resulting in net proceeds of approximately $19.3 million and representing the entire capacity of the ATM.

- In February 2020, the Company entered into a senior secured term loan credit facility 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.

Fourth Quarter Financial Results

- **Cash and cash equivalents:** As of December 31, 2019, Agile had $34.5 million of cash and cash equivalents compared to $7.9 million of cash and cash equivalents as of December 31, 2018. The Company believes its cash and cash equivalents as of December 31, 2019, along with the proceeds of the Perceptive credit agreement received to date, will be sufficient to meet its projected operating requirements through the end of 2020. The Company will require additional capital to fund operating needs beyond 2020, which it expects primarily will consist of commercializing Twirla, and exploring the advancement of our existing pipeline and its possible expansion through business development activities.

- **Research and development (R&D) expenses:** R&D expenses were $2.7 million for the quarter ended December 31, 2019 and $9.9 million for the year ended December 31, 2019, compared to $1.9 million and $9.8 million for the comparable periods in 2018. The increase in R&D expenses was primarily due to consulting fees and costs associated with the preparation for and attendance at the FDA advisory committee meeting as well as costs associated with the on-going qualification process of the commercial manufacturing equipment at Corium.

- **General and administrative (G&A) expenses:** G&A expenses were $3.3 million for the quarter ended December 31, 2019 and $9.0 million for the year ended December 31, 2019, compared to $1.6 million and $8.7 million for the comparable periods in 2018. The increase in G&A expenses was primarily due to the use of financial consultants, recruiting and search fees and an increase in promotional activities as the Company prepares for the commercialization of Twirla.

- **Net loss:** Net loss was $6.0 million, or $0.10 per share, for the quarter ended December 31, 2019, compared to a net loss of $3.8 million, or $0.11 per share, for the quarter ended December 31, 2018. Net loss for the year ended December 31, 2019 was $18.6 million, or $0.38 per share, compared to a net loss of $19.8 million, or $0.58 per share, for the year ended December 31, 2018.

- **Shares Outstanding:** At February 18, 2020, Agile had 69,810,305 shares of common stock outstanding.

About Twirla®

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is 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, 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 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 the suppliers to our third-party manufacturer, 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, 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)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 34,479	$ 7,851
Prepaid expenses	840	607
Total current assets	35,319	8,458
Property and equipment, net	14,044	13,916
Other assets	177	18
Total assets	$ 49,540	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,623	$ 2,218
Lease liability, current portion	172	-
Total liabilities	3,795	2,218
Stockholders' equity		
Common stock	7	3
Additional paid-in capital	306,108	261,722
Accumulated deficit	(260,370)	(241,551)
Total stockholders' equity	45,745	20,174
Total liabilities and stockholders' equity	$ 49,540	$ 22,392

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 2,728	$ 1,856	$ 9,858	$ 9,777
General and administrative	3,337	1,567	9,000	8,739
Restructuring costs	—	304	—	1,019
Total operating expenses	6,105	3,727	18,858	19,535
Loss from operations	(6,105)	(3,727)	(18,858)	(19,535)
Other income (expense)				
Interest income	84	77	252	366
Interest expense	—	(160)	—	(1,116)
Change in fair value of warrants	—	—	—	29
Loss before benefit from income taxes	(6,021)	(3,810)	(18,606)	(20,256)
Benefit from income taxes	—	—	—	477
Net loss	$ (6,021)	$ (3,810)	$ (18,606)	$ (19,779)
Net loss per share - basic and diluted	$ (0.10)	$ (0.11)	$ (0.38)	$ (0.58)
Weighted-average shares outstanding –basic and diluted	62,559,514	34,377,329	49,432,487	34,315,931