

**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**

**March 1, 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:

<b>Title of Each Class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 March 1, 2021, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2020 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.**

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release dated March 1, 2021.</a>

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## 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: March 1, 2021

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

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**AGILE THERAPEUTICS REPORTS FOURTH QUARTER & FULL YEAR 2020 FINANCIAL RESULTS;  
EXPANDS LOAN FACILITY WITH PERCEPTIVE ADVISORS**

*Perceptive Advisors Increases Credit Facility to \$45 million, with \$25 million potentially available*

*Achieved Gross Revenue Target In Fourth Quarter 2020, Reflecting Initial Stocking of Twirla®  
(levonorgestrel and ethinyl estradiol) transdermal system*

*Announces Agreement with Sterling Specialty Pharmacy*

PRINCETON, N.J., March 1, 2021 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today reported financial results for the three and twelve months ended December 31, 2020 and provided a corporate update.

“We closed out 2020 on a high note with the commercial launch of Twirla® in December, following the approval by the U.S. Food and Drug Administration. Supported by the tireless efforts of the entire Agile team, a dedicated sales force and broad wholesaler relationships, we shipped commercial product to wholesalers in our targeted time frame and we believe we are now well-positioned to continue our early launch momentum with strong interest continuing to support Twirla's growth,” said Al Altomari, Chairman and Chief Executive Officer of Agile. “We continue to be optimistic about Twirla's trajectory, which we expect to be further supported by our new partnership with Sterling Specialty Pharmacy and bolstered by the increased flexibility from the remaining \$25 million potentially available from Perceptive Advisors.”

**Recent Corporate Developments, Financing Update and Fourth Quarter & Full Year 2020 Results:*****Twirla and Company Updates***

- In 2020, The Company entered into distribution agreements with three major U.S. wholesalers, as well as several regional wholesalers.
- In the fourth quarter of 2020, Agile finalized the validation of its commercial manufacturing process of Twirla and commenced commercial shipments of product to wholesalers in December 2020.
- On February 24, 2021, the Company entered into an agreement with Sterling Specialty Pharmacy – a company that shares our patient-first philosophy – which we believe will play a critical role in accelerating the uptake of Twirla by making it easy for providers to prescribe and convenient for patients to receive their filled prescription.

- The Company expects that Twirla will now become available to the members of one of the country's largest closed health care systems, based on a recently negotiated group purchasing organization agreement, which will provide another channel for patients to access Twirla.
- Agile continued with its payor engagement strategy for obtaining coverage and reimbursement for Twirla and estimates it has achieved approximately 40-45% commercial formulary coverage so far— inclusive of one of the three major pharmacy benefit managers and other smaller plans. Efforts to increase formulary access are ongoing.
- The Company continues to build awareness among prescribers, to drive increased traction and support market access for Twirla. Sampling efforts are ongoing and the compounded weekly prescription (TRx) growth rate shows early momentum in the launch. Additionally, the Company is beginning to see units dispersed at pharmacies as refills.
- Agile hired Dr. Paul Korner, M.D., as the Chief Medical Officer in August 2020. Dr. Korner is leading an evaluation of our existing pipeline, including potential development costs and timelines. The Company is also exploring potential expansion through business development opportunities.
- In 2020, through Syneos Selling Solutions, the Company's contract sales force partner, Agile hired and deployed a sales force of 8 regional virtual sales specialists and 65 sales professionals; a total of 73 individuals calling on the healthcare provider ("HCP") audience. Since launch, the sales force has been able to conduct roughly 70% of prescriber meetings face-to-face in a COVID-19 compliant setting.

#### ***I'm So Done – A National Unbranded Awareness 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. We are encouraged by our preliminary results, which include:
  - o High levels of engagement with our website content via display and paid social efforts, which has empowered women to join in the birth control conversation.
  - o Agile is breaking the status quo of the contraceptive category, introducing the first birth control awareness campaign on TikTok, the most downloaded app of 2020.

#### ***Financing Update – Expanded Loan Facility with Perceptive Advisors***

- In February 2020, Agile entered into a senior secured term loan credit facility with Perceptive Advisors (Perceptive), which provided support for the commercialization of Twirla. Of the initial \$35 million in funding provided by Perceptive, \$20 million was drawn down by Agile in 2020 and \$15 million is remaining through 2021, available upon the achievement of certain revenue milestones.

- Perceptive Advisors is now providing an additional \$10 million through our loan facility, under a fourth tranche. This amount will be available through June 2022 and is also contingent on achieving a pre-determined revenue target.
- In total, our funding available from Perceptive Advisors has increased to \$45 million and reflects continued support from a well-regarded leader in growth capital financing.
- This strategic debt financing, along with our cash balance, puts the Company in a position to not only cover projected operating requirements in 2021, but also provides Agile with increased financial flexibility going forward.
- Finally, with the pandemic impact continuing into this year, should the impact of COVID-19 or other factors impact the Company's current business plans or its ability to generate revenue from 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.

#### ***Fourth Quarter and Full Year 2020 Financial Results***

- **Gross revenue:** As guided, the Company achieved just over \$1 million in gross revenue in the fourth quarter, reflecting the initial stocking of Twirla into the channel.
- **Cash, cash equivalents and marketable securities:** As of December 31, 2020, Agile had \$54.5 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 \$3.0 million for the quarter ended December 31, 2020, compared to \$2.8 million for the comparable period in 2019. For the full year, R&D expenses were \$13.5 million in 2020, and \$9.9 million in 2019. The increase in year-over-year R&D expenses was primarily due to costs to validate the commercial manufacturing process for Twirla by Corium, the Company's contract manufacturer, as well as clinical development and personnel-related expenses.
- **Selling and marketing expenses:** Selling and marketing expenses were \$10.7 million for the quarter ended December 31, 2020, compared to \$0.8 million for the comparable period in 2019. For the full year, selling and marketing expenses were \$23.3 million in 2020, and \$1.1 million in 2019. The increase in year-over-year selling and marketing expenses was due to higher costs associated with the Company's pre-commercialization activities for Twirla, such as brand building, advocacy, market research and consulting, and the costs of establishing and maintaining our contract sales force.

- **General and administrative (G&A) expenses:** G&A expenses were \$3.5 million for the quarter ended December 31, 2020, compared to \$2.5 million for the comparable period in 2019. For the full year, G&A expenses were \$12.7 million in 2020, and \$7.9 million in 2019. The increase in year-over-year G&A expenses reflected activities related to build out the support infrastructure including higher personnel costs and professional fees, as well as an increase in stock compensation expense.
- **Net loss:** Net loss was \$17.6 million, or \$0.20 per share, for the quarter ended December 31, 2020, compared to a net loss of \$6.0 million, or \$0.10 per share, for the comparable period in 2019. For the full year, net loss was \$51.9 million, or \$0.61 per share in 2020, compared to a net loss of \$18.6 million, or \$0.38 per share in 2019.
- **Shares Outstanding:** Agile had 87,563,753 shares of common stock outstanding at year end 2020.

### Conference Call and Webcast

Agile Therapeutics will host a conference call and webcast to discuss financial results for the third quarter ended March 1, 2021, today at 4:30 pm ET. Investors and other interested parties may participate by registering for a teleconference line or live webcast link 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/m<sup>2</sup> 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<sup>2</sup> before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m<sup>2</sup>. Twirla is 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 forward-looking 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), a 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](http://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®, the development of our other potential product candidates, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures and our expected financing needs and sources of financing, including our debt financing from Perceptive Advisors. 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 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 amount 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:

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

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,463	\$ 34,479
Marketable securities	40,008	—
Accounts receivable, net	865	—
Prepaid expenses	1,449	840
<b>Total current assets</b>	<b>56,785</b>	<b>35,319</b>
Property and equipment, net	14,243	14,044
Right of use asset	138	158
Other non-current assets	1,896	19
<b>Total assets</b>	<b>\$ 73,062</b>	<b>\$ 49,540</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,867	\$ 1,819
Accrued expenses	3,348	1,804
Lease liability, current portion	138	172
<b>Total current liabilities</b>	<b>7,353</b>	<b>3,795</b>
Long-term debt	16,381	—
<b>Total liabilities</b>	<b>23,734</b>	<b>3,795</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 87,563,753 and 69,810,305 issued and outstanding at December 31, 2020 and December 31, 2019, respectively	9	7
Additional paid-in capital	361,539	306,108
Accumulated other comprehensive income	3	—
Accumulated deficit	(312,223)	(260,370)
<b>Total stockholders' equity</b>	<b>49,328</b>	<b>45,745</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 73,062</b>	<b>\$ 49,540</b>



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

	Three Months Ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Revenues, net	\$ 749	\$ —	\$ 749	\$ —
Cost of product revenues	282	—	282	—
Gross profit	<u>467</u>	<u>—</u>	<u>467</u>	<u>—</u>
Operating expenses:				
Research and development	\$ 3,011	\$ 2,837	\$ 13,500	\$ 9,858
Selling and marketing	10,670	755	23,285	1,085
General and administrative	3,527	2,513	12,735	7,915
Total operating expenses	<u>17,208</u>	<u>6,105</u>	<u>49,520</u>	<u>18,858</u>
Loss from operations	<u>(16,741)</u>	<u>(6,105)</u>	<u>(49,053)</u>	<u>(18,858)</u>
Other income (expense)				
Interest income	25	84	309	252
Interest expense	(904)	—	(3,109)	—
Total other income (expense), net	<u>(879)</u>	<u>84</u>	<u>(2,800)</u>	<u>252</u>
Loss before benefit from income taxes	<u>(17,620)</u>	<u>(6,021)</u>	<u>(51,853)</u>	<u>(18,606)</u>
Benefit from income taxes	—	—	—	—
Net loss	<u>\$ (17,620)</u>	<u>\$ (6,021)</u>	<u>\$ (51,853)</u>	<u>\$ (18,606)</u>
Net loss per share (basic and diluted)	<u>\$ (0.20)</u>	<u>\$ (0.10)</u>	<u>\$ (0.61)</u>	<u>\$ (0.38)</u>
Weighted-average common shares (basic and diluted)	<u>87,448,501</u>	<u>62,559,514</u>	<u>84,683,084</u>	<u>49,432,487</u>