

**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 30, 2022**

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.)

**500 College Road East, Suite 310**  
**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 March 30, 2022, Agile Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2021 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.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release dated March 30, 2022.</a>
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

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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 30, 2022

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

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**AGILE THERAPEUTICS REPORTS FOURTH QUARTER & FULL YEAR 2021 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE**

*Twirla Demand Grows with Cycles Dispensed and Total Prescriptions (TRx) Up 35% and 33% Respectively in Fourth Quarter 2021 vs Third Quarter 2021*

*New Twirla Connected TV Commercial Expected to launch in April 2022 and Contribute to Further Demand Growth*

*Company Advances Business Plan Designed to Target Resources on Building Momentum for Twirla*

*Management to Host Conference Call Today, Wednesday, March 30, 2022 at 4:30 p.m. ET*

PRINCETON, N.J., March 30, 2022 (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, 2021 and provided a corporate update.

“2021 was our first full year of commercializing Twirla, and I am proud of what our team was able to accomplish. We believe we created a solid foundation for further Twirla growth in 2022 through targeted partnerships and allocation of our marketing spend in key markets,” said Agile Therapeutics Chairman and Chief Executive Officer Al Altomari. “We ended 2021 with double digit growth in demand quarter over quarter and expect to see that continue in the first quarter of 2022. We are also excited to launch our first CTV commercial in April 2022. We believe we can continue to build momentum through 2022, with this targeted business plan.”

***Fourth Quarter and Corporate Updates***

- During the fourth quarter 2021, Twirla experienced double digit demand growth. From the end of the third quarter to the end of the fourth quarter 2021, key metrics for Twirla demand increased:
    - Total cycles dispensed grew 32%
    - Total prescriptions (TRx) grew 33%
    - New prescriptions (NRx) grew 22%
    - Refills grew 44%
    - Total prescribers grew 24%
  
  - The Company's business plan for 2022 is focused on growing demand for Twirla. Key elements include:
    - Partnership with Afaxys
      - In January 2022, the Company launched a co-promotion program with Afaxys, through their group purchasing organization (GPO), which primarily provides services to the non-retail channel, and Afaxys Pharma, which has potential access to over 25,000 accounts, including college and university student health centers and Planned Parenthoods.
      - The Company believes the alliance with Afaxys can drive non-retail growth and expects to see the contribution from this channel ramp throughout 2022.
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- Targeted Focus on California
    - The Company has placed a targeted focus on California, the largest U.S. market for contraceptives, through preferred positioning on Medi-Cal formulary.
    - Medi-Cal provides healthcare to approximately 15 million beneficiaries, and with Twirla now active on the Medi-Cal formulary, increasing Twirla awareness and adoption in California through direct-to-consumer (DTC) marketing is a priority.
  - Launch of DTC Commercial on Connected TV (CTV)
    - The Company is launching its first connected TV (or CTV) advertisement, focusing on women in the targeted Twirla age demographic of 18-24 years in the key states of California, Texas, Florida, Illinois, and New York. All 5 of these states have large markets for contraceptives and potentially strong commercial coverage for Twirla.
    - The Company believes the targeted markets mentioned above reach approximately 41 – 45% of the current patient base, representing an opportunity to effectively and efficiently grow our market share.
    - The Company's CTV ad is expected to launch in early April 2022.
  - In January 2022, the U.S. Departments of Labor, Health and Human Services (HHS) and Treasury, updated guidelines reinforcing the requirement for most commercial insurers and PBMs to cover all FDA-approved contraceptives at no cost, if deemed medically necessary by a provider. Additionally, The Health Resources Service Administration (HRSA) updated their women's preventative service guidelines for plan years beginning in 2023 to include that coverage of all FDA-approved, granted or cleared contraceptives be made available as part of contraceptive care. These updated guidelines are potentially significant for Twirla and will be monitored throughout 2022.
  - Updates on financing activities:
    - The Company has no further plans to add additional funds under the debt facility with Perceptive Advisors ("Perceptive"). In January 2022, the Company repaid \$5 million in debt from Perceptive, reducing its debt to \$15 million in exchange for relief on certain financial covenants. The Company plans to make an additional \$5 million payment to Perceptive in the second quarter 2022.
    - In March 2022, the Company closed a \$4.85 million registered direct offering of preferred stock with a single healthcare-focused institutional investor.
    - The Company expects to receive an estimated \$4.7 million in funds from the sale of New Jersey net operating losses through a program run by the State of New Jersey in the second quarter 2022.
    - The Company has called a Special Meeting of Stockholders to be held on April 21, 2022, in order to seek approval for an amendment to its certificate of incorporation to implement a reverse stock split. The amendment is intended to allow the Company to regain compliance with the Nasdaq listing requirements.
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#### ***Fourth Quarter and Full Year 2021 Financial Results***

- **Net revenue:** In the fourth quarter 2021, the Company realized net product sales revenue of \$1.5 million, which was at the high end of the range guided by the Company in January 2022. Revenue for the full year 2021 was \$4.1 million.
  - **Cost of product revenues:** Cost of product revenues for the fourth quarter 2021 was \$5.7 million, which included a \$4.5 million inventory obsolescence charge for product not expected to be sold prior to its shelf-life date, which is 12 months prior to expiry. Full year cost of product revenue was \$10.7 million, including \$5.9 million of inventory obsolescence reserves.
  - **Total operating expenses:** Total operating expenses were \$18.2 million for the quarter ended December 31, 2021, compared to \$17.2 million for the comparable period in 2020. Full year operating expenses were \$64.4 million compared to \$49.5 million in 2020. The overall increase is primarily related to consumer-based marketing efforts and the sales force, which was in place for the full year of 2021.
  - **Cash and cash equivalents:** As of December 31, 2021, the Company had \$19.1 million of cash and cash equivalents, compared to \$14.7 million of cash and cash equivalents as of the end of the third quarter 2021. The increase in cash on hand is related to a public offering completed in the fourth quarter, netting \$21.1 million, offset by working capital burn during the quarter.
  - **Net loss:** Net loss was \$23.4 million, or \$0.20 per share, for the quarter ended December 31, 2021, compared to a net loss of \$17.6 million, or \$0.20 per share, for the comparable period in 2020. For the full year, net loss was \$74.9 million in 2021, or \$0.77 per share, compared to a net loss of \$51.9 million, or \$0.61 per share, in 2020.
  - **Shares Outstanding:** Agile had 121,396,033 shares of common stock outstanding at year end 2021.
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## Conference Call and Webcast

Date	Wednesday, March 30, 2022
Time	4:30 p.m. EDT
Webcast (live and archived)	<b>Events &amp; Presentations</b>
Dial-in numbers	(833) 979-2857 (U.S. toll-free) or (236) 714-2948
Conference ID	7088441

Investors interested in listening to the conference call may do so by dialing (833) 979-2857 for domestic callers or (236) 714-2948 for international callers. The required Conference ID is 7088441. 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/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 also 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 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) 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, including the increasing demand for Twirla, our partnership with Afaxys and its ability to promote

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growth, regulatory and legislative developments in the United States, our future plans with respect to our existing debt financing from Perceptive Advisors, our receipt of funds from the sale of net operating losses in New Jersey, our ability to come into compliance with the listing requirements of Nasdaq, our results of operations, revenues, financial condition, liquidity, prospects, growth and strategies, and the expected benefits of our marketing and sales distribution strategies generally. 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 and the market demand for Twirla, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla, 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 come into compliance with the listing requirements of Nasdaq 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

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

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 19,143	\$ 14,463
Marketable securities	—	40,008
Accounts receivable, net	1,533	865
Inventory, net	966	—
Prepaid expenses and other current assets	2,283	1,449
Total current assets	23,925	56,785
Property and equipment, net	12,447	14,243
Right of use asset	949	138
Other non-current assets	2,012	1,896
<b>Total assets</b>	<b>\$ 39,333</b>	<b>\$ 73,062</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Long-term debt, current portion	\$ 16,833	\$ —
Accounts payable	8,707	3,867
Accrued expenses	3,563	3,348
Lease liability, current portion	175	138
Total current liabilities	29,278	7,353
Lease liabilities, long-term	784	—
Long-term debt	—	16,381
<b>Total liabilities</b>	30,062	23,734
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock, \$.0001 par value, 150,000,000 shares authorized, 121,396,033 and 87,563,753 issued and outstanding at 12/31/21 and 12/31/20, respectively	12	9
Additional paid-in capital	396,376	361,539
Accumulated other comprehensive income	—	3
Accumulated deficit	(387,117)	(312,223)
<b>Total stockholders' equity</b>	9,271	49,328
<b>Total liabilities and stockholders' equity</b>	<b>\$ 39,333</b>	<b>\$ 73,062</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,	
	2021	2020	2021	2020
Revenues, net	\$ 1,514	\$ 749	\$ 4,101	\$ 749
Cost of product revenues	5,702	282	10,718	282
Gross profit	<u>(4,188)</u>	<u>467</u>	<u>(6,617)</u>	<u>467</u>
Operating expenses:				
Research and development	\$ 1,656	\$ 3,011	\$ 6,246	\$ 13,500
Selling and marketing	12,670	10,670	43,444	23,285
General and administrative	3,846	3,527	14,698	12,735
Total operating expenses	<u>18,172</u>	<u>17,208</u>	<u>64,388</u>	<u>49,520</u>
Loss from operations	<u>(22,360)</u>	<u>(16,741)</u>	<u>(71,005)</u>	<u>(49,053)</u>
Other income (expense)				
Interest income	1	25	25	309
Interest expense	<u>(999)</u>	<u>(904)</u>	<u>(3,914)</u>	<u>(3,109)</u>
Total other income (expense), net	<u>(998)</u>	<u>(879)</u>	<u>(3,889)</u>	<u>(2,800)</u>
Net loss	<u>\$ (23,358)</u>	<u>\$ (17,620)</u>	<u>\$ (74,894)</u>	<u>\$ (51,853)</u>
Net loss per share (basic and diluted)	<u>\$ (0.20)</u>	<u>\$ (0.20)</u>	<u>\$ (0.77)</u>	<u>\$ (0.61)</u>
Weighted-average common shares (basic and diluted)	<u>117,917,775</u>	<u>87,448,501</u>	<u>97,072,847</u>	<u>84,683,084</u>

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