

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

April 9, 2024  
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
N/A	N/A	None

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.**

In April 2024, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company expects first quarter 2024 Twirla demand to be approximately 81,000 total cycles. The Company expects factory sales in the first quarter 2024 to be slightly less than demand as the distribution channels normalize.

Because the Company's financial statements for the quarter ended March 31, 2024 have not yet been finalized or reviewed, these preliminary statements regarding the Company's demand and factory sales for the quarter ended March 31, 2024 are subject to change, and the Company's actual demand and factory sales during these periods may differ materially from these preliminary estimates. Accordingly, you should not place undue reliance on these preliminary estimates.

**Item 7.01. Regulation FD Disclosure.**

The information set forth in Item 2.02 of this Current Report on Form 8-K (this "Report") is incorporated into this Item 7.01 by reference.

A copy of the Company's updated corporate presentation is attached hereto as Exhibit 99.1.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in Items 2.02 and 7.01 of this Report, including Exhibits 99.1 and 99.2 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="#">Agile Therapeutics, Inc. Corporate Presentation dated April 2024</a>
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).



**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: April 9, 2024

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

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# Agile Therapeutics Company Presentation

April 2024

# Forward-Looking Statements

Certain information contained in this presentation 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 in 2024, our partnership with Afaxys and its ability to promote growth, our product supply agreement with Nurx and its ability to educate patients about Twirla, our connected TV (CTV) campaign and its ability to promote growth, our prospects for future financing arrangements, and our financial condition, growth and strategies. 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 raise additional capital, ability to pay our obligations as they become due, ability to maintain regulatory approval of Twirla and the labeling under any approval we obtain, the ability of Corium to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully enhance the commercialization of and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets, regulatory and legislative developments in the United States and foreign countries, our ability to obtain and maintain intellectual property protection for Twirla and our product candidates, clinical trials, supply chain, operations and the operations of third parties we rely on for services such as manufacturing, marketing support and sales support, 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.



# Company & Product Overview

## Who We Are

- Agile Therapeutics® is a commercial-stage women's healthcare company dedicated to fulfilling the unmet health needs of today's women
- Our product and product candidates are designed to offer women more freedom and flexibility through additional contraceptive options
- Currently focused on growth of our first FDA-approved product Twirla® (levonorgestrel and ethinyl estradiol) transdermal system
- Headquartered in Princeton, NJ



# Twirla® is the first and only birth control patch delivering a low dose of estrogen.<sup>1-5</sup>

## A LOWER ESTROGEN DOSE THAN OTHER CONTRACEPTIVE PATCHES

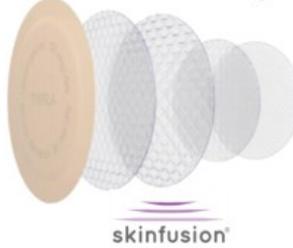
Twirla delivers 30 mcg of estrogen daily, **the lowest exposure of estrogen in a transdermal contraceptive option.**<sup>2-4</sup>



Not actual size  
For illustrative purposes only.

## WOVEN, FLEXIBLE FABRIC

Only Twirla uses **Skinfusion® patch technology** for consistent drug delivery and to help maintain adhesion. Twirla is made with a soft, flexible fabric designed to contour with a woman's body.



skinfusion®

## DEMONSTRATED SAFETY PROFILE

In the SECURE Trial, conducted in a large and diverse group of women, **Twirla was found to be a safe and well-tolerated weekly option** in women with a BMI <30 kg/m<sup>2</sup> for whom a combined hormonal contraceptive is appropriate.<sup>1,2</sup>

## PURPOSEFULLY INCLUSIVE TRIAL

Efficacy and safety were established in a purposefully inclusive trial that featured a diverse study population, **closely representative of the demographics of women across the US.**<sup>1</sup>

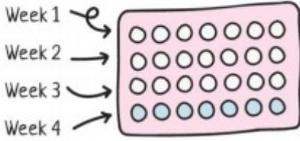
Twirla® is a weekly hormonal birth control patch for women with a body mass index (BMI) less than 30 kg/m<sup>2</sup> who can become pregnant. Twirla is less effective in women with a BMI of 25 kg/m<sup>2</sup> or more and should not be used in women whose BMI is 30 kg/m<sup>2</sup> or more.

**References:** 1. Nelson AL, Kauritz AM, Kroil R, et al. Efficacy, safety, and tolerability of a levonorgestrel/ethinyl estradiol transdermal delivery system: phase 3 clinical trial results. *Contraception*. 2021;103(3):137-143. 2. Twirla [prescribing information]. Princeton, NJ: Agile Therapeutics, Inc.; 2020. 3. Xulane [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; 2020. 4. Zafemy [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2021. 5. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Morb Mortal Wkly Rep*. 2016;65(3):1-104.

# Twirla: Birth Control Designed to Fit Her Life

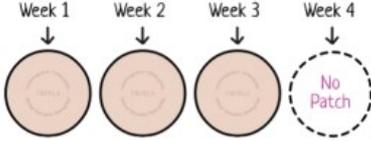
**Weekly. Self-Administered. Just 3 Patches a Month.**

### THE DAILY PILL ROUTINE:



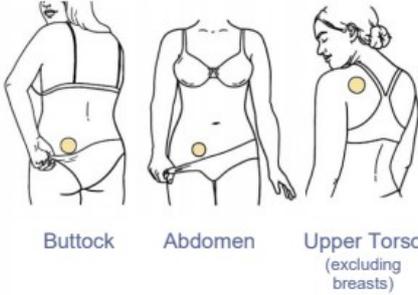
Stop and take it every day, ideally at the same time each day for at least 21 days each month.

### WITH TWIRLA, SHE CHANGES THE PATCH JUST ONCE A WEEK FOR 3 WEEKS EACH MONTH



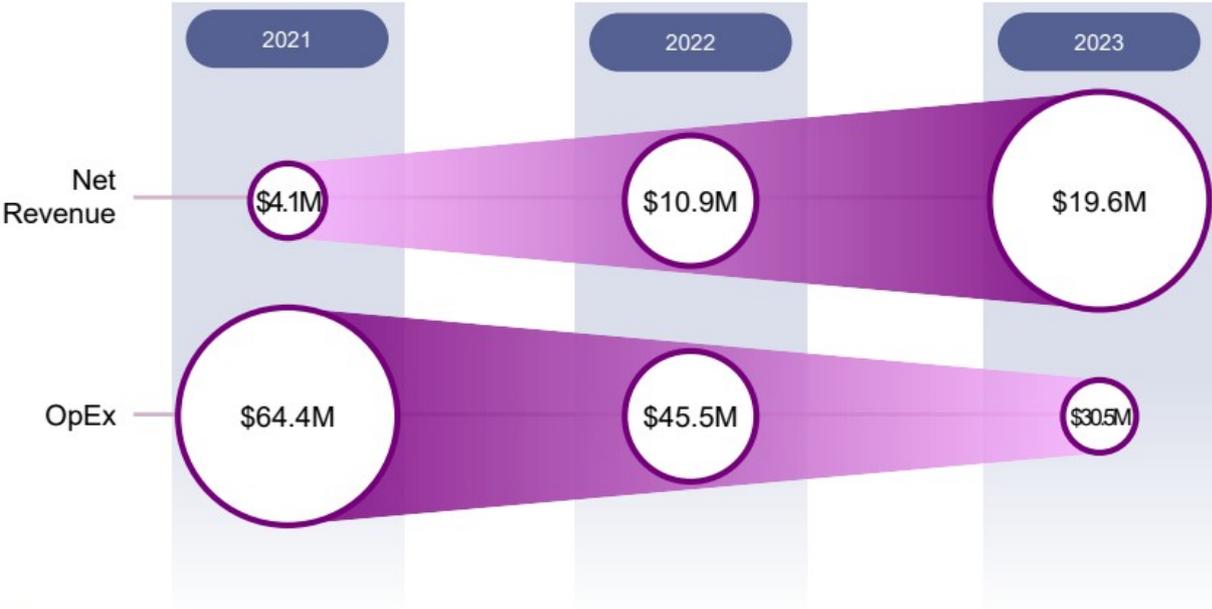
During the fourth week of the cycle, she wears no patch and should expect her period.

### TWIRLA MAY BE APPLIED TO ONE OF THE FOLLOWING LOCATIONS ON THE SKIN



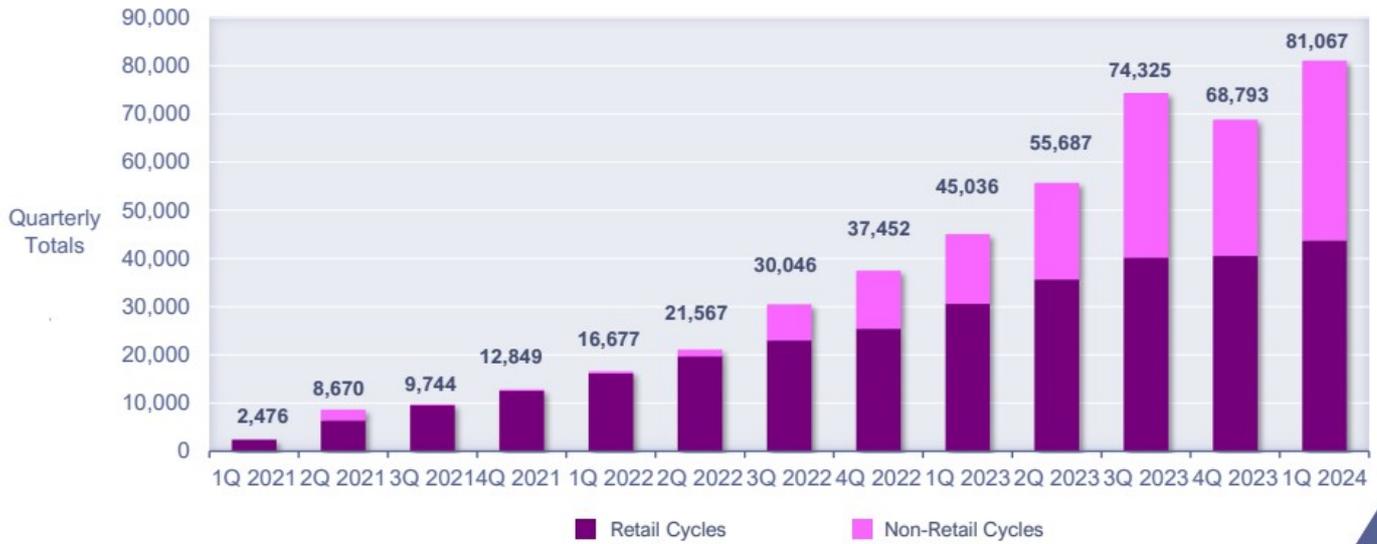
# Twirla Performance Update

# Year-Over-Year Net Revenue & OpEx Improvement



# Twirla Quarterly Demand

## Demand Rebound from Q4 2023 is Occurring\*



\* First quarter 2024 demand numbers are estimates and subject to quarter close procedures; demand does not include telemedicine providers.

# Demand Rebound from Q4 2023 is Occurring\*

Q1 2024: Record High (Retail, Non-Retail and Total Cycles)  
 March 2024 Record High (Total Cycles)



\* First quarter 2024 demand numbers are estimates and subject to quarter close procedures; demand does not include telemedicine providers.

# Year-Over-Year Twirla Demand Improvement



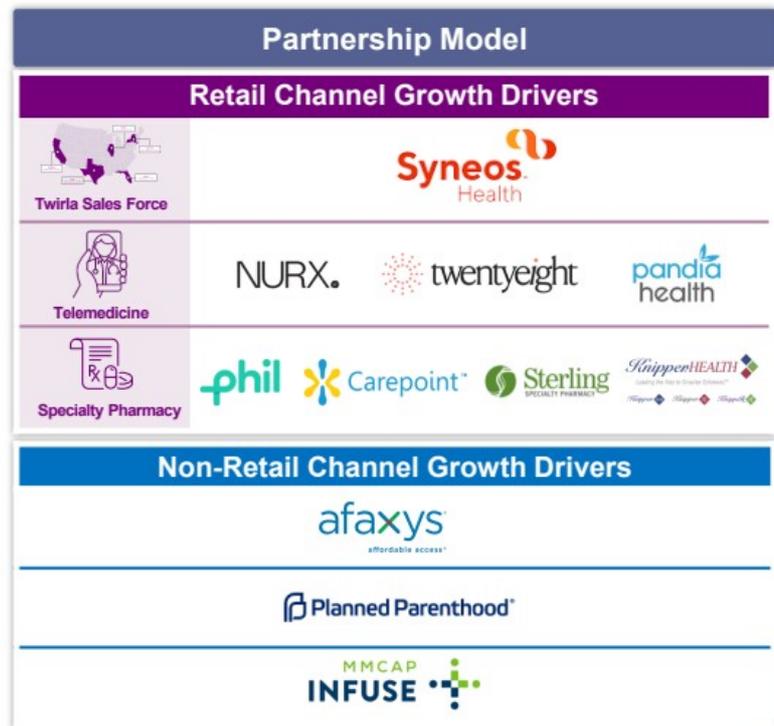
# Factory Sales (Cycles) and Managed OpEx



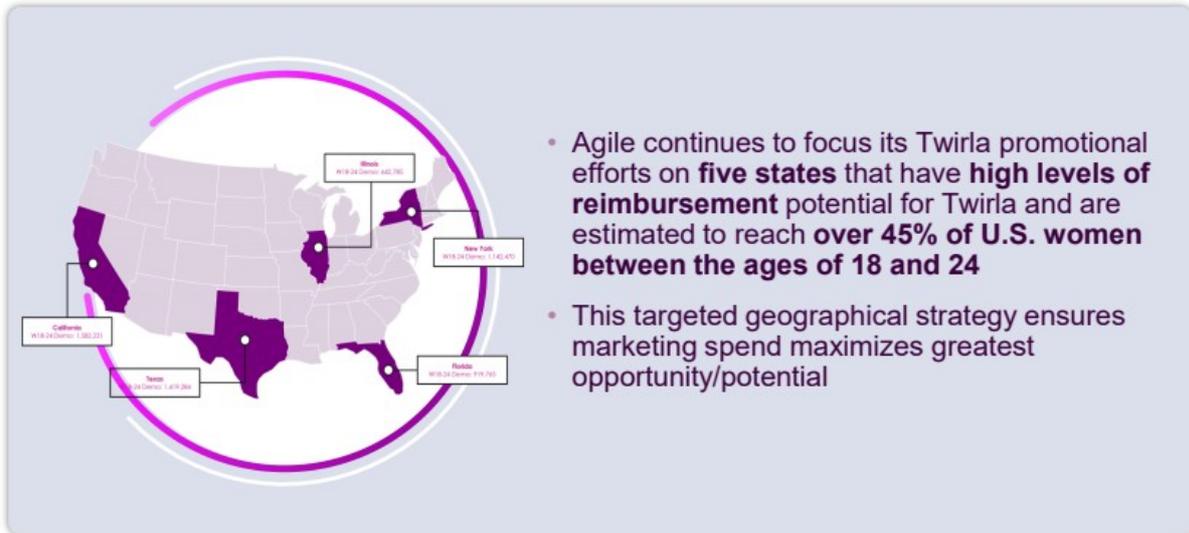
# Twirla Business Plan: Potential For Further Upside

# Twirla Business Plan Goal

- Capital-Efficient Business That Can Generate Sustainable Growth



# Targeting “Big 5” States



- Agile continues to focus its Twirla promotional efforts on **five states** that have **high levels of reimbursement** potential for Twirla and are estimated to reach **over 45% of U.S. women between the ages of 18 and 24**
- This targeted geographical strategy ensures marketing spend maximizes greatest opportunity/potential

## Retail Channel Growth Driver: Telemedicine



- Collaboration with female telemedicine leader Nurx will make **Twirla an available option to Nurx patients.**
- Nurx medical providers have prescribed contraception to **more than 1 million patients.**
- **Shared marketing initiative designed to raise Twirla awareness** among Nurx's large contraceptive patient network.
- Full launch of Nurx collaboration occurred in fourth quarter 2022 and **impact on the retail channel expected to be realized in 2024.**

## Non-Retail Channel Growth Driver: Afaxys Partnership



- **Non-retail demand grew 330% (22,533 to 96,843 total cycles) in 2023 compared to 2022.**
- **Growth driven by Afaxys-led promotion to the Planned Parenthood network.**
- Recent performance includes **conversion of Planned Parenthood accounts in California.**
- The Company believes there is **additional potential for Twirla volume growth** in this channel based on the reach of the Afaxys customer network.

# Potential Breakthrough for Access to Contraceptive Products like Twirla® Resolution Appears Prioritized and Imminent

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## Health insurers have long ignored a federal law to cover birth control. Biden's new executive order could force them to comply

BY MARIA ASPAN AND KINSEY CROWLEY  
June 28, 2023, at 8:24 AM EDT

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FEATURES · BIRTH CONTROL

## President Biden's new executive order could help American women get better birth control

BY MARIA ASPAN  
June 27, 2023, at 3:36 AM EDT

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### President Biden's Executive Order on Contraception Directs Agencies To

- 1 Reduce** barriers that women with private insurance face in accessing contraception
- 2 Improve** access to affordable over-the-counter contraception, including emergency contraception
- 3 Expand** access to affordable family planning services across the Medicaid program
- 4 Improve** access for Medicare beneficiaries
- 5 Support** research on contraception access and family planning
- 6 Ensure** robust coverage of contraception for service members, veterans, and federal employees
- 7 Support** employees and higher ed students in accessing contraception

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