

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

September 10, 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:

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 7.01. Regulation FD Disclosure.

Agile Therapeutics, Inc. (the "Company") has updated the corporate presentation that it intends to use at the H.C. Wainwright 23rd Annual Global Investment Conference beginning on September 13, 2021 and subsequent investor conferences. The Company may use the presentation in meetings with investors from time to time as well. The updates primarily involve financial projections for the third quarter of 2021 on net revenue and retail units sold based on total prescription demand for Twirla® (levonorgestrel and ethinyl estradiol) transdermal system. The Company estimates that net sales in the third quarter of 2021 will be in the range of \$1.4 million to \$1.6 million, and retail units sold based on total prescription demand will be 9,500 to 10,000. The update also reiterates the Company's financial projection of operating expenses for the second half of 2021, which the Company expects to be at levels similar to its second quarter of 2021 spending within a range of \$1 million to \$2 million. Because the Company's financial statements for the quarter ended September 30, 2021 have not yet been finalized or reviewed, this financial projection regarding the Company's expected net revenue, units sold and operating expense is subject to change, and the Company's results as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

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 this Report 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.

Forward-Looking Statements

Certain information contained in this Report may include "forward-looking statements." Our use of terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes may identify these forward-looking statements.

In particular, statements regarding our projected third quarter 2021 net revenue, retail units sold based on total prescription demand for Twirla, and operating expenses for the second half of 2021 are examples of such forward-looking statements. Such forward-looking statements are subject to important risks and uncertainties, including, but not limited to, risks related to our ability to maintain regulatory approval of Twirla, the ability of our third party manufacturer, Corium, to produce commercial supply in quantities and quality sufficient to satisfy market demand for Twirla, our ability to successfully commercialize and obtain market access for Twirla, the successful development of our sales and marketing capabilities, the accuracy of our estimates of the potential market for Twirla, our ability to achieve our target formulary access goals, 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 on as well as on our potential customer base, unforeseen market factors or events in our clinical, regulatory and manufacturing development plans, and other factors, including general economic conditions and regulatory developments, not within the Company's control.

These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. These forward-looking statements are made only as of the date of this Report and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in "Risk Factors" in the Company's periodic reports filed with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1 104	Agile Therapeutics, Inc. Presentation dated September 2021. Cover Page Interactive Data File (embedded with 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: September 10, 2021

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

Agile Therapeutics (AGRX) Corporate Presentation

September 2021

Forward-Looking Statements

Certain information contained in this presentation and other matters discussed today or answers that may be given in response to questions may include “forward-looking statements.” We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of 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 size of our addressable market, our results of operations, our estimates on the net sales and number of units sold based on total prescription demand for Twirla in the third quarter 2021 and operating expenses for the second half of 2021, 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. These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. These forward-looking statements are made only as of the date of this presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Who We Are




NASDAQ: AGRX



Who We Are

- A commercial-stage company dedicated to building a robust Women's Health Franchise
- Headquartered in Princeton, NJ
- Currently focused on contraception, specifically our first FDA-approved product Twirla®
- Senior leadership largely comprised of J&J alumni responsible for the launch of Ortho Evra



Establish Agile in
Contraceptive Market
with Twirla

Become Contraceptive
Market Leader

Broaden Women's
Health Portfolio in
Areas of Unmet Need

Agile[®]
THERAPEUTICS

NASDAQ: AGRX

Our Product

Agile[®]
THERAPEUTICS

NASDAQ: AGRX

Twirla® Snapshot

- Twirla® (levonorgestrel and ethinyl estradiol) transdermal system launched in December 2020
 - A once-weekly, non-invasive contraceptive patch
 - Twirla is the first and only patch to deliver a low dose of estrogen along with a 120 mcg daily dose of levonorgestrel, a well-known progestin with a long history of use in the category
 - 69 Sales Professionals (Syneos CSO) Aligned to Highest-Volume Geographies and Target Provider Offices
 - Twirla enters a \$4.1B addressable market

TWIRLA is indicated as a method of contraception for use in women with a BMI < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Consider TWIRLA's reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m² before prescribing TWIRLA. TWIRLA is contraindicated in women with a BMI ≥ 30 kg/m².

Agile[®] THERAPEUTICS NASDAQ: AGRX



Considerations for Hormonal Contraceptive Choices

"Some women are just not good at remembering to take a pill at the same time every day...Others don't want something in their vagina while others don't want an injection."

- Ob/Gyn

LOWER
ESTROGEN
DOSE

The dose of estrogen in CHCs is believed to be the primary factor contributing to unwanted side effects

The only other non-daily transdermal patch currently available delivers high dose of estrogen²

NON-
DAILY
OPTIONS

Potential to reduce burden associated with daily pill

49% of contraception users prefer non-daily method³

52% are frustrated with taking the pill daily³

LESS
INVASIVE
METHODS

May be preferred by some women⁴

Some women prefer to avoid injections, implants, and intrauterine devices



NASDAQ: AGRX

1-Poindexter, A., Fertility and Sterility 2001; 2-Xulane Package Insert; 3-Mansour D., International Journal of Women's Health 2014; 4- Qualitative and quantitative HCP research, Kantar Health 2010; Third party research, 2017

Twirla Designed to Fill A Hormonal Birth Control Market Need

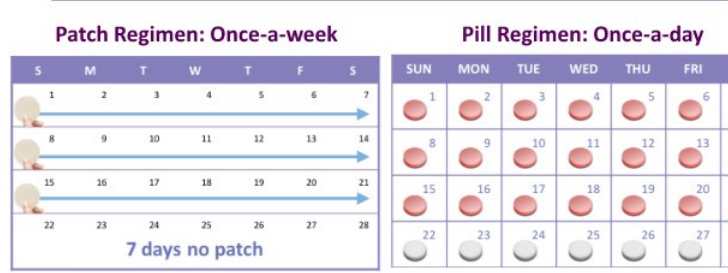


Not actual size.
For illustrative purposes only.

HORMONE
PROFILE

30µg/day Ethinyl Estradiol (EE)
120µg/day Levonorgestrel (LNG)

NON-
DAILY



LESS
INVASIVE

Less invasive than some methods
(vaginal ring, IUDs, injections, implants)

"I want to eliminate the forgetfulness... but I don't want to lose that control either."

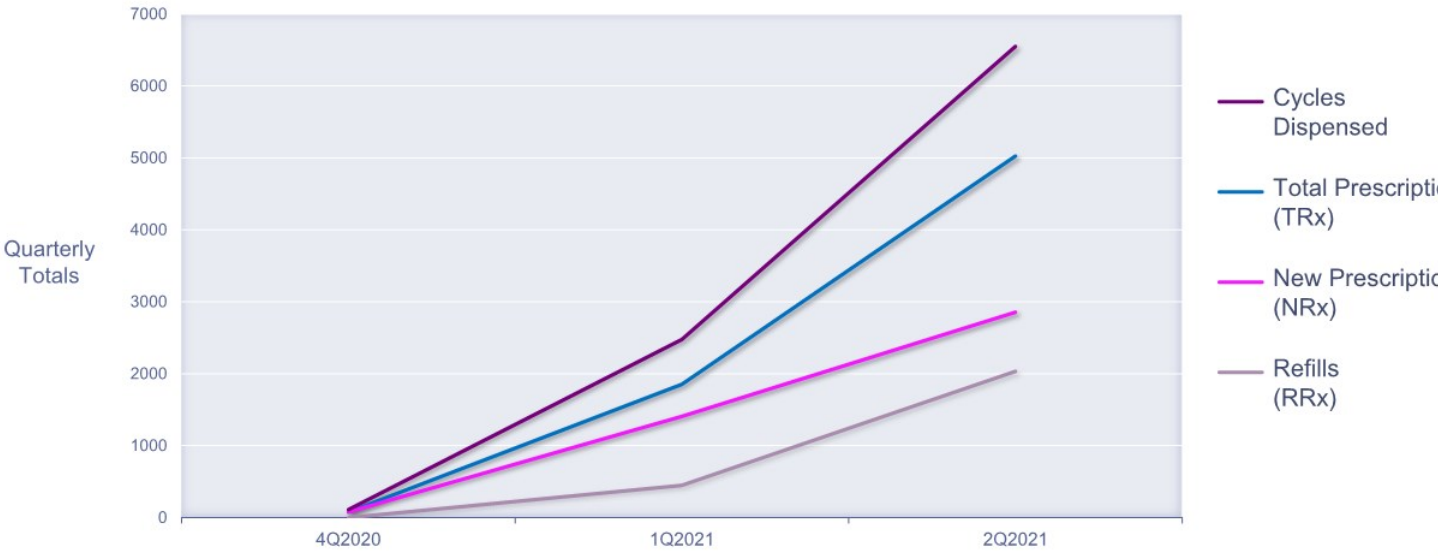
– Consumer Market Research

Where We Are

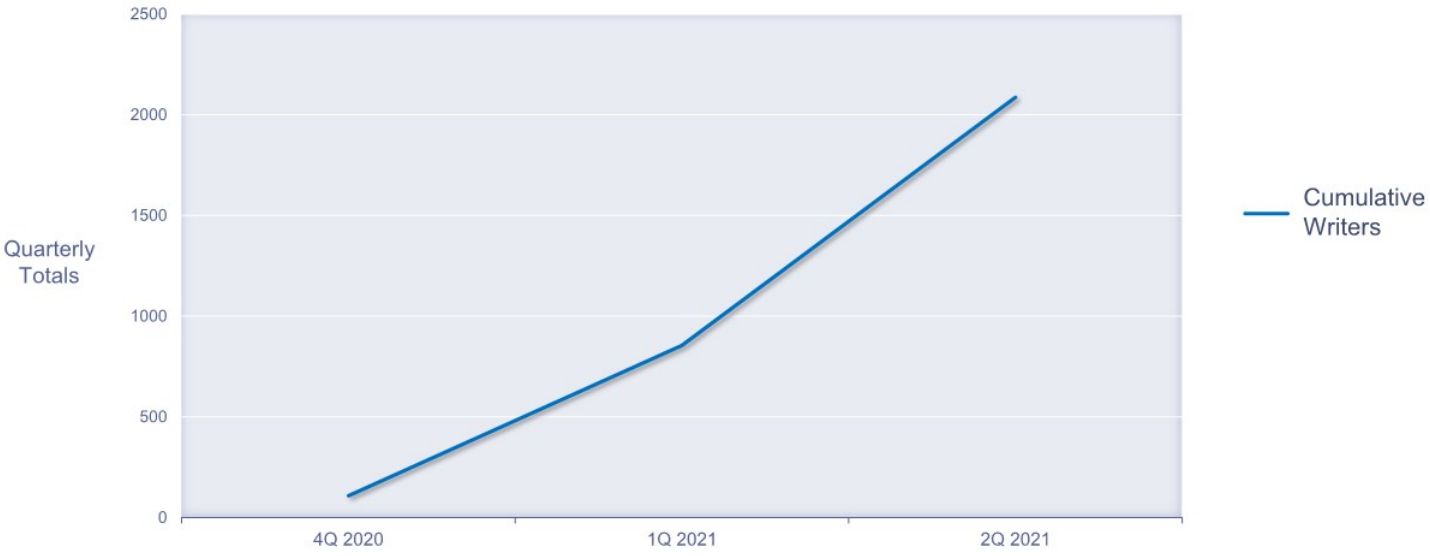
Agile[®]
THERAPEUTICS

NASDAQ: AGRX

Twirla Growth Based on Key Performance Metrics (Quarterly)



Growing Number of Twirla Prescribers (Quarterly)



How We Plan to Accelerate Growth



NASDAQ: AGRX

Immediate Impact on Tinder

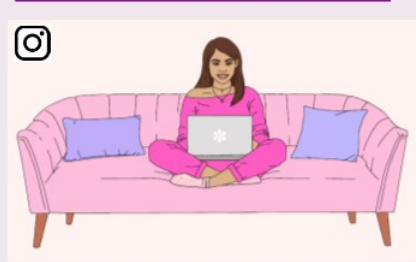


Exceeding company expectations weeks into launch

Expanding Twirla Digital Presence in 2H 2022



Influencer Activation



Minimize Access Barriers for Patients

- Twirla is now available to Medicaid patients in approximately 75% of states either through traditional Medicaid and/or managed Medicaid. With these new additions, Twirla now has coverage in approximately 50% of the total Medicaid transdermal TRx market with no restrictions.
- Overall, Twirla has access in approximately 55% of the commercial and government CHC market based on claims.
- In addition to progress on Medicaid and Managed Care access, the Company also saw expanded access through state clinics, where there was significant non-retail prescription volume in the second quarter 2021.
- Additional access support:
 - Third-party support to facilitate timely submission of prior authorizations for patient access
 - Co-Pay card reimbursement assistance
 - Full-month samples for patient trial



NASDAQ: AGRX

Recent Partnership Announcement



AGILE THERAPEUTICS PARTNERS WITH TELEHEALTH SERVICE, PANDIA HEALTH, TO INCREASE WOMEN'S ACCESS TO TWIRLA® (LEVONORGESTREL AND ETHINYL ESTRADIOL) TRANSDERMAL SYSTEM

August 20, 2021

[PDF Version](#)

- Pandia Health is a doctor founded and led telehealth company, offering online prescriptions and free delivery designed to make it easier for women to access birth control options that meet their needs
- Partnership represents first telehealth alliance for Agile's Twirla® birth control patch

PRINCETON, N.J., Aug. 20, 2021 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today announced a partnership with Pandia Health, an online telehealth service, which will establish the first telehealth relationship for Agile and offer an additional point of access to Twirla® (levonorgestrel and ethinyl estradiol) transdermal system in a fast-growing channel.

Pandia Health offers convenient prescription fulfillment for women with active birth control prescriptions, as well as access to expert birth control doctors who can provide prescriptions through asynchronous online visits. All patients receive free delivery of their birth control. The Company and Pandia plan to phase in the availability of Twirla in the second half of 2021.



NASDAQ: AGRX

Beyond Twirla®

Agile®
THERAPEUTICS

NASDAQ: AGRX

Commitment to Enhancing Shareholder Value

The Company believes that building a U.S. women's health franchise on the foundation of Twirla's commercial success can enhance value for our shareholders. A successful launch of Twirla is our primary focus.

- Reevaluation and planning potential development of our internal pipeline candidates is on-going in 2021
- We are open to potentially acquiring new assets to expand our reach in women's health

We have sought out and will continue to explore partnerships and opportunities that leverage our existing infrastructure:

- Co-promotion within the U.S.
- Partnerships outside of the U.S.
- Any other opportunities that have the potential to enhance shareholder value

Financial Update



NASDAQ: AGRX

Financial Update & Company Outlook

Second Quarter 2021 Results

Net product sales revenue of \$1.2 million reflected market demand as we completed our inventory drawdown.

Total expenses were in-line with expectations, addressing commercialization activities for Twirla

Near-Term Outlook

Revenue expected to more closely reflect TRx demand in 2H21 and wholesaler restocking

Operating expense at similar levels to Q2 spending in 2H21 within a range of \$1- \$2 million as a result of continued spending on commercial costs from product samples, branded marketing and potential inventory reserves.

Financial Flexibility

- \$30.1 million cash, cash equivalents and marketable securities as of June 30, 2021, a potential access to additional capital under existing loan facility subject to financial milestones
- Potential to access additional capital through at-the-market arrangement to sell up to \$50 million of company common stock.



We Continue to Focus on Growth in Q3 2021

Agile continues to focus on growing sales of Twirla in both the retail and non-retail channels. We are seeking to expand access to Twirla through initiatives like the recent collaboration with telemedicine provider, Pandia Health.

Progress in the Retail channel. Estimated Q3 2021 retail units (cycles) sold based on script demand is expected to be in the range of 9,500 to 10,000 units, which would reflect an estimated 50% to 56% quarterly growth over the 6,400 retail units sold in Q2 2021.

We seek to cultivate strategic Institutional Accounts. We do not expect meaningful sales into the non-retail institutional channel in 3Q 2021 but continue to explore developing institutional accounts. In Q2 2021 we had a significant purchase of 2,100 units of Twirla.

Revenue outlook for Q3 2021. As previously guided, we expect net sales from our retail accounts to reflect more closely TRx script demand, with each script representing 1.3 cycles or monthly prescriptions of Twirla (3 patches). We estimate Q3 2021 net sales will be in the range of \$1.4 million to \$1.6 million.