

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**

January 9, 2023
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.

As discussed below, in connection with its participation in the 41st Annual J.P. Morgan Healthcare Conference beginning on January 9th, 2023, Agile Therapeutics, Inc. (the “Company”) updated its corporate presentation to include disclosure that the Company expects fourth quarter 2022 Twirla factory sales to be approximately 43,200 total cycles and full year 2022 Twirla factory sales to be approximately 113,600 total cycles. The updated presentation also includes disclosure that the Company expects full year 2023 net revenue to be in the range of \$25 million to \$30 million and that operating expenses are expected to remain similar to the second half of 2022.

Because the Company’s financial statements for the quarter and year ended December 31, 2022 have not yet been finalized or audited, this preliminary statement regarding the Company’s factory sales for the quarter and year ended December 31, 2022 is subject to change, and the Company’s actual 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.

Beginning on January 9, 2023, the Company will participate in the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California. The Company has updated its corporate presentation to include the above-disclosed information for use at investor conferences, including the J.P. Morgan Healthcare Conference.

In addition, on January 9, 2023, the Company issued a press release providing similar information to the updates provided in its corporate presentation.

A copy of the Company’s updated corporate presentation is attached hereto as Exhibit 99.1 and a copy of the press release is attached hereto as Exhibit 99.2.

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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Agile Therapeutics, Inc. Corporate Presentation dated January 2023
99.2	Press Release dated January 9, 2023.
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: January 9, 2023

By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: Chairman and Chief Executive Officer

Agile Therapeutics Corporate Presentation

January 2023

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” 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,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of future events or outcomes to 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 our projections regarding our net revenue and operating expenses for 2023, 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 the fourth quarter of 2022 and 2023, 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 future plans with respect to additional commercial products, our ability to become cash flow positive, 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 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, that factory sales for the fourth quarter of 2022 are not final and may be subject to change, 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, the effects of the ongoing COVID-19 pandemic on our commercialization efforts, 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, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market 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.¹⁻⁵

A LOWER ESTROGEN DOSE THAN OTHER CONTRACEPTIVE PATCHES

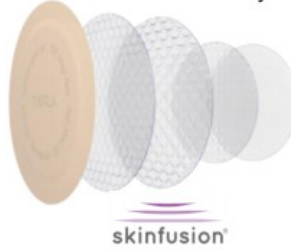
Twirla delivers 30 mcg of estrogen daily, **the lowest exposure of estrogen in a transdermal contraceptive option.**²⁻⁴



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/m² for whom a combined hormonal contraceptive is appropriate.^{1,2}

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.**¹

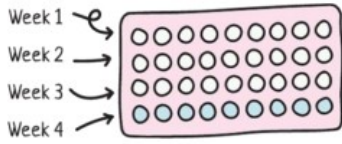
Twirla® is a weekly hormonal birth control patch for women with a body mass index (BMI) less than 30 kg/m² who can become pregnant. Twirla is less effective in women with a BMI of 25 kg/m² or more and should not be used in women whose BMI is 30 kg/m² or more.

References: 1. Nelson AL, Kauritz AM, Kroll 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

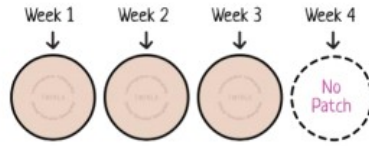
Weekly. Self-Administered. Just 3 Patches a Month.

THE DAILY PILL ROUTINE:



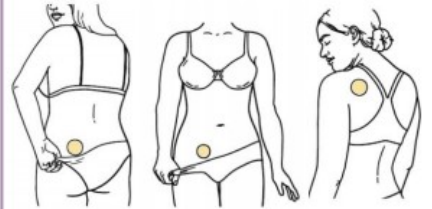
Stop and take it every day, ideally at the same time each day for at least 21 days each month.

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



Buttock

Abdomen

Upper Torso
(excluding
breasts)

Current Focus: Grow Twirla & Generate Positive Cash Flow

**Establish Agile in
Contraceptive Market
by Growing Twirla®**

Become a Contraceptive
Market Leader

Broaden Women's
Health Portfolio in Areas
of Unmet Need

Twirla Performance Update

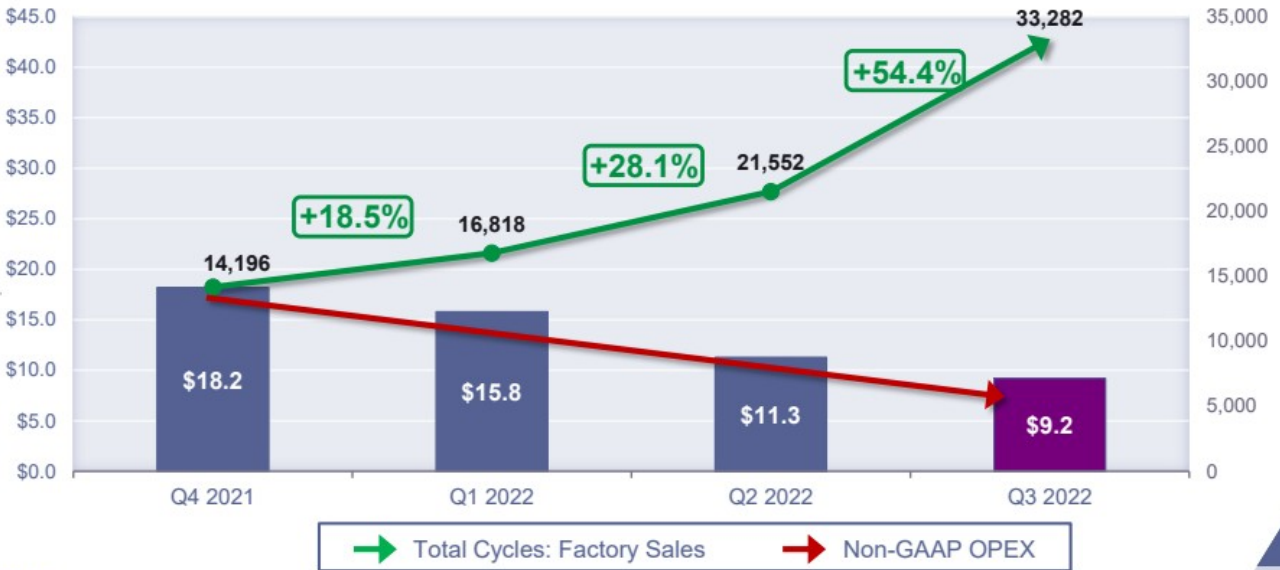
Q3 2022 Net Revenue Growth

	Q3 2022	Q2 2022	% Change
Net Revenue (vs. Q2 2022)	\$3.0M	\$2.1M	+43%
	Q3 2022	Q3 2021	% Change
Net Revenue (vs. Q3 2021)	\$3.0M	\$1.3M	+131%

Twirla Demand: Retail vs. Non-Retail (Quarterly)



Consecutive Quarters of Accelerated Factory Sales Growth (Cycles) and Reduced Non-GAAP OPEX



NASDAQ: AGRX

Reconciliations of non-GAAP to GAAP financial measures are available in our third quarter 2022 earnings press release and elsewhere in this presentation.

Q3 2022 Results: Business Plan is Performing

	Q3 2022 vs. Q2 2022			Q3 2022 vs. Q3 2021	
	Q3 2022	Q2 2022	% Change	Q3 2021	% Change
Net Revenue	\$3.0M	\$2.1M	+43%	\$1.3M	+131%
Non-GAAP OPEX	\$9.2M	\$11.3M	-19%	\$14.4M	-36%
	YTD 2022 vs. YTD 2021				
	Thru Sept. 30, 2022	Thru Sept. 30, 2021	% Change		
Net Revenue	\$6.9M	\$2.6M	+165%		
Non-GAAP OPEX	\$36.3M	\$46.3M	-22%		



NASDAQ: AGRX

Reconciliations of non-GAAP to GAAP financial measures are available in our third quarter 2022 earnings press release and elsewhere in this presentation.

Fourth Quarter 2022 Update & Full Year 2023 Outlook

Fourth Quarter 2022 Twirla Factory Sales Expected to be approximately 43,200 Total Cycles – a 30% Increase from Third Quarter 2022

Full Year 2022 Twirla Factory Sales Expected to be approximately 113,600 Total Cycles – a 232% Increase from Full Year 2021

Full Year 2023 Net Revenue Expected to be in Range of \$25-\$30 Million with OPEX Levels Expected to Remain Similar to Second Half 2022

Company is Actively Pursuing Business Development Opportunities Focused on Adding Commercial Women's Health Products and Potentially Reducing Timeline Required to Generate Positive Cash Flow

Twirla Business Plan: Potential For Further Upside

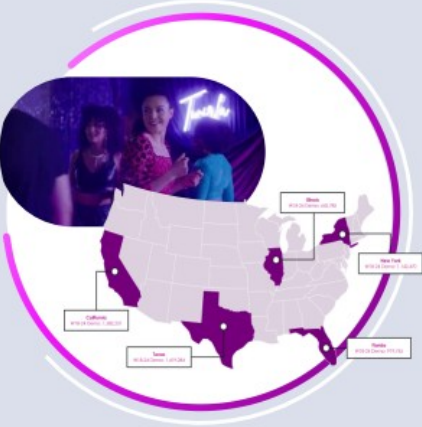
Non-Retail Channel Growth Driver: Afaxys Partnership



The image shows the logos for Afaxys and Planned Parenthood. The Afaxys logo is in blue and green with the tagline 'affordable access' below it. The Planned Parenthood logo is in blue and black. Both are enclosed in a circular graphic with a purple and white border.

- From the end of the second quarter 2022 to the end of the third quarter 2022, **non-retail cycles purchased grew 361% (1,404 to 6,479).**
- **Growth driven by Afaxys-led promotion** to the Planned Parenthood network.
- Third quarter included **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.

Retail Channel Growth Driver: Twirla CTV Commercial



- Relunched promotion of **DTC Connected TV (CTV) commercial** to coincide with **back-to-school months**, which have historically been active time of year for contraception decisions
- Targeted focus on five states with potentially strong Twirla reimbursement coverage estimated to reach **45% of U.S. women between ages 18-24**
- Initial run of CTV commercial in April garnered positive results that helped **raise awareness, trial, and adoption** of Twirla

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 2023.**

Potential Upside to our Plan for Growth in Second Half 2022 & Beyond

Non-Retail Growth Driver



Retail Growth Drivers



Business Plan for Growth in 2H22



Grow Twirla & Generate Positive Cash Flow

Potential Upside for Growth



- If ACA coverage of new contraceptives like Twirla improves, greater growth upside can potentially be achieved
- Agile will continue to execute on established business plan to grow Twirla and we believe plan can achieve Company profitability despite ACA challenges



We Believe Strategic Partnerships Can Help us Expand our Business

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. Continued growth of Twirla is our primary focus.

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.
- Other opportunities that will enhance shareholder value

Beyond Twirla, opportunities include:

- Evaluation of our internal pipeline candidates will continue throughout 2022
- Exploring potential acquisition of new assets to expand our reach in women's health

Appendix

Summary of Lack of Compliance with ACA Contraceptive Mandate

Health
The ACA has a birth control guarantee. Senators are pushing for better enforcement.

Patients and health care providers have reported e medical bills that should not be permitted under t

Insurance Companies Are Giving Ridiculous Reasons For Not Covering New Birth Control Methods

Private insurers are doing everything they can to shirk the government's birth control coverage requirement.

DENIED

The ACA guarantees full contraceptive coverage. Why are women getting denied?

With access to a high-quality insurance company and paying the cost they should be able to get it.
By Shannon Shaker Miller | Feb 23, 2016
ACCESS & AFFORDABILITY
ISSUES

Politics
(Not so) free birth control: White House puts pressure on insurance companies over ACA requirement

- The ACA requires health plans and insurers to cover all contraceptives at \$0 cost share if determined to be the most medically appropriate.
- We have heard from both patients and providers about challenges in obtaining the product that has been deemed most appropriate for them by some insurers.
- With the overturning of **Roe v. Wade**, it is critical that women do not encounter barriers when trying to obtain the contraceptive that will work best for them
- Agile Therapeutics continues to work with both patients and providers to make them aware of our product and the ability to have a lower dose option in a transdermal contraceptive.
- Agile Therapeutics is appreciative of the work by the **Biden administration to ensure all women have access to the birth control product** that has been deemed most appropriate for them in discussions between them and their provider.
- As plans begin to evaluate their practices to comply with requirements, **access to newer contraceptives like Twirla is expected to improve**

Reconciliation of Non-GAAP Financial Measures (unaudited)

	Three Months Ended					Nine Months Ended September 30,	
	Q3 2022	Q2 2022	Q1 2022	Q4 2021	Q3 2021	2022	2021
GAAP Operating expenses	\$20,285	\$11,293	\$15,807	\$18,170	\$14,350	\$47,383	\$46,217
Non-GAAP adjustment: Loss on disposition of assets	\$11,122	-	-	-	-	\$11,122	-
Non-GAAP operating expenses	\$ 9,163	\$11,293	\$11,293	\$11,293	\$14,350	\$36,261	\$46,217

AGILE THERAPEUTICS PROVIDES UPDATES ON 2022 TWIRLA PERFORMANCE AND 2023 COMMERCIAL PLAN

Fourth Quarter 2022 Twirla Factory Sales Expected to Increase Approximately 30% from Third Quarter 2022

Full Year 2022 Factory Sales Expected to Increase Approximately 232% from Full Year 2021

Full Year 2023 Net Revenue Expected to be in Range of \$25-\$30 Million

PRINCETON, N.J., January 9, 2023 (GLOBE NEWSWIRE) – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, today provided an update on Twirla for 2022 and its commercial plan for 2023.

2022 Twirla Factory Sales

- o Twirla factory sales for the fourth quarter 2022 are expected to be approximately 43,200 total cycles, a 30% increase from the 33,282 total cycles reported for the third quarter 2022. The approximately 43,200 total cycles would represent an all-time high for single-quarter factory sales.
- o Twirla factory sales for the full year 2022 are expected to be approximately 113,600 total cycles, a 232% increase from the 34,227 total cycles reported for the full year 2021.

“Our first commercial product, Twirla, demonstrated accelerated growth in the second half of 2022 and now we are excited to enter 2023 with strong growth momentum,” said Agile Therapeutics' Chairman and Chief Executive Officer Al Altomari. “We expect to see that trend continue throughout 2023, even as we plan to hold our operating expenses at levels similar to the second half of 2022.”

2023 Commercial Plan

The Company's commercial plan for 2023 is designed to continue growing demand for Twirla in both the retail and non-retail channels in key states that have large markets for contraceptives and potentially strong reimbursement coverage for Twirla (“Key States”). To accomplish this growth on the retail side, the Company intends to focus on increasing its footprint in telemedicine through its collaboration with Nurx, which has a patient network of more than 1 million patients, and targeted marketing in Key States to increase depth of prescribing. In the non-retail channel, the Company plans to continue to focus on growth through the reach of the Afaxys customer network, which includes Planned Parenthood and student health centers. The Company also believes it will start to see increased growth in the retail channel as physicians who gain clinical experience with Twirla in the Planned Parenthood setting and then prescribe Twirla in their other practices. The Company is also actively pursuing business development opportunities focused on adding commercial products to the Company's women's health franchise.

- **2023 Net Revenue**

- o Based on its commercial plan for 2023, the Company expects increased revenue contributions from the Twirla business in 2023 and full year net revenue to be in the range of \$25-\$30 million. The Company plans to maintain operating expenses at similar levels to the second half of 2022.
-

Mr. Altomari stated, “the entire organization remains focused on achieving our key goals of growing Twirla, generating positive cash flow, and pursuing opportunities to build our business. We believe we have built a capable commercial infrastructure, proven the ability to consistently grow our first commercial product over the past challenging year, managed our operating expenses in a targeted way, and laid the foundation for building a broader women’s health business. We think that these qualities make us an attractive commercial partner. Based on our current business plan, we expect that adding an additional commercial product to our portfolio would reduce the time required to generate positive cash flow and accelerate our growth as a company. We are actively pursuing these types of opportunities.”

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. The Company may occasionally disseminate material, nonpublic information on the Company’s website, Twitter account (@agilether), and LinkedIn account.

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/m² 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/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². 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 Prescription Data

The Company receives prescription data for Twirla from Symphony Health Solutions, and the data are not created or owned by the Company. Prescription data are available through other subscription services as well, such as IQVIA. Not all prescription demand in the non-retail channel is reported into third parties like Symphony Health Solutions and IQVIA. The factory sales reported from Twirla wholesalers do include sales to the non-retail channel and, therefore, the Company believes factory sales more closely represent the total demand for Twirla across all channels.

Forward-Looking Statements

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 our projections regarding our net revenue and operating expenses for 2023,

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 the fourth quarter of 2022 and 2023, 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 future plans with respect to additional commercial products, our ability to become cash flow positive, 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 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, that factory sales for the fourth quarter of 2022 are not final and may be subject to change, 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, the effects of the ongoing COVID-19 pandemic on our commercialization efforts, 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, our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market 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

mriley@agiletherapeutics.com
