

Proprietary Transdermal Products Company fulfilling the healthcare needs of Today's Women Agile Therapeutics NASDAQ: AGRX

Healthcare Company dedicated to fulfilling the unmet health needs of today's Modern Women: Agile Therapeutics (NASDAQ: AGRX)

PRINCETON, NEW JERSEY, UNITED STATES, July 6, 2021 / EINPresswire.com/ -- Women's Healthcare Company dedicated to fulfilling the unmet health needs of today's Modern Women: [Agile Therapeutics \(NASDAQ: AGRX\)](https://www.agiletherapeutics.com)

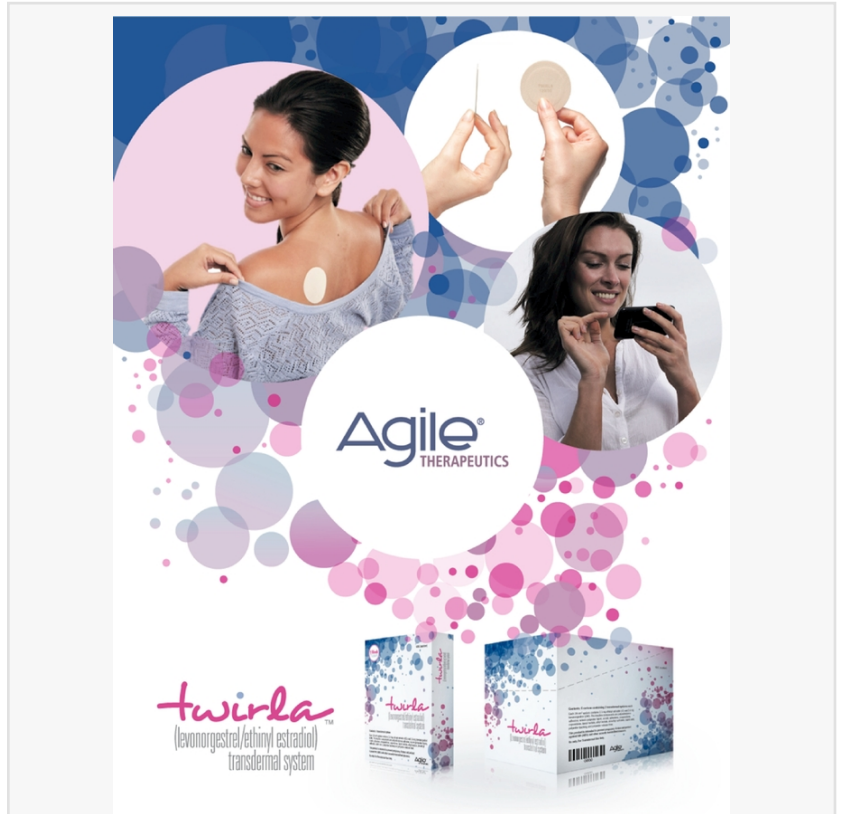
Women's Healthcare Company with Proprietary Transdermal Products.

Focus on Innovative Alternatives to Oral Contraception for Modern Women.

Prescription Growth Reflects Increasing Demand for Twirla Product.

Growing Distribution Network and Marketing Efforts Expected to Drive Healthcare Provider and Consumer Engagement.

Presentation Given at 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting.



Agile Therapeutics AGRX on the NASDAQ

<p>April 30, 2021 Agile Therapeutics Announces Presentation of Safety and Efficacy Data of Twirla® (Levonorgestrel and Ethinyl Estradiol) Transdermal System in Women of Differing BMI Categories at ACOG Annual Meeting</p>	<p>April 20, 2021 Agile Therapeutics to Report First Quarter 2021 Financial Results and Provide Business Update on Tuesday, May 4, 2020</p>	<p>March 05, 2021 Agile Therapeutics to Present at Upcoming March Investor Conferences</p>	<p>March 01, 2021 Agile Therapeutics Reports Fourth Quarter & Full Year 2020 Financial Results: Expands Loan Facility With Perceptive Advisors</p>	<p>February 19, 2021 Agile Therapeutics to Host Fourth Quarter and Full Year 2020 Financial Results Conference Call and Provide Corporate and Twirla Commercial Updates on Monday, March 1, 2021</p>
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AGILE THERAPEUTICS PIPELINE

Our pipeline reflects our commitment to bringing women the healthcare choices they deserve. All current Agile Therapeutics product and product candidates use our proprietary Skinfusion® Technology.

[RESEARCH >](#)

OUR FIRST APPROVED PRODUCT

LEARN ABOUT TWIRLA® >

AGILE THERAPEUTICS LEADERSHIP TEAM

Commitment. Passion. Drive.

These are the qualities that make us who we are. From the top down.

[MEET OUR EXECUTIVE LEADERSHIP TEAM >](#)

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AGRX Pipeline

Agile Therapeutics (NASDAQ: AGRX) is a forward-looking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. AGRX 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. The initial AGRX product, Twirla®, (levonorgestrel and ethinyl estradiol), a transdermal system, is a non-daily prescription contraceptive. Twirla is based on AGRX proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin.

AGRX Twirla

□ First Quarter 2021 Update



At Agile, we are committed to addressing the needs of women through our products and the generation of new analyses”

*Paul Korner, MD, MBA, AGRX
Chief Medical Officer*

On May 4th AGRX gave a corporate update for the three months ended March 31, 2021.

Twirla Performance and Updates

During the first quarter 2021, total prescriptions were 1,853. The growth was driven by an increase in the number of prescribers, which as of March 31, 2021 was more than 850 HCPs, and growing refill rates. As of March 31, 2021,

447 of prescriptions dispensed at pharmacies were refills. AGRX also saw an increase in the number of total prescriptions by prescriber.

□ AGRX believes its momentum in prescriptions reflects underlying demand for Twirla and is supported by steady growth in the first quarter, which has continued into the early second quarter.

□ AGRX continues to focus on expanding access and reimbursement coverage for Twirla across managed care and government health insurance plans. During the first quarter 2021, AGRX made progress in obtaining Medicaid coverage for Twirla. Currently, Twirla is covered with no prior authorization in 20 states with expected coverage pending in Texas in May 2021. The Medicaid market represents a large number of combined hormonal contraceptive (“CHC”) users; Medicaid volumes for oral CHC total prescriptions in 2020 were nearly eight million.

In February 2021, AGRX entered into a specialty distribution agreement with Sterling Specialty Pharmacy (“Sterling”). AGRX believes that the relationship with Sterling will facilitate increased access to Twirla based on early results, which have been productive in increasing uptake of Twirla. AGRX continues to explore the potential to expand its distribution network through other channels that can support growth of Twirla demand including telemedicine.

Marketing Campaign Updates

AGRX continues to support I’m So Done, an education and empowerment unbranded awareness campaign that encourages women to think about their current contraceptive method and decision-making journey. AGRX has seen increased activity on its website and various applications, including Tik Tok.

Beginning in the second quarter AGRX plans to shift a significant portion of its investment in marketing to its branded campaign. AGRX plans to focus its branded campaign efforts on driving awareness and trial of Twirla, with a goal of meeting women throughout their everyday routine with a targeted digital strategy. Ongoing efforts include a multi-channel creative campaign that positions Twirla as the first and only weekly contraceptive patch that delivers a low dose of estrogen. AGRX plans to expand its digital reach to other applications including Tinder and OkCupid, as well as Spotify. These three applications reach millions of U.S. women between the ages of 18 and 34 on a monthly basis.

Financial Update

AGRX has \$25 million of capital potentially available through its loan facility with Perceptive Advisors, including a tranche of \$15 million in 2021, and a tranche of \$10 million, which will be available through June 2022, both contingent on achieving a pre-determined revenue target.

Twirla® is our Lead Product Candidate

Twirla is a once-weekly contraceptive patch

- Designed to deliver a low daily dose of estrogen, comparable to a low dose oral contraceptive
- Only one other contraceptive patch is available in the US, and delivers a higher dose of estrogen

Women want alternatives to a daily birth control pill

- Chief complaint is fitting daily pills into their busy lifestyles
- Women frequently forget to take their pill (1-4x per month)

Positive Phase 3 Clinical Trial Data Announced January 2017

Agile Therapeutics
NASDAQ: AGRX

Sources: Qualitative consumer and HCP market research, RG&A 2012; ACE Survey 2013. Data on File, Agile Therapeutics

AGRX Twirla 2

AGRX Birth Control

□ Additionally, AGRX has the potential to access additional capital through its existing at-the-market arrangement, under which AGRX may sell up to an aggregate of \$50 million in gross proceeds through the sale of shares of common stock.

□ AGRX Presentation of Safety and Efficacy Data on TWIRLA[®] (LEVONORGESTREL and ETHINYL ESTRADIOL) Transdermal System in Women of Differing BMI Categories

On April 30th AGRX announced that a post hoc analysis of the Phase 3 SECURE Trial evaluating the safety and efficacy of its Twirla[®] (levonorgestrel and ethinyl estradiol) transdermal system in women with BMI < 25 kg/m² and women with BMI 25-30 kg/m² would be presented at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting from April 30 – May 2.

The AGRX Twirla product was approved based on the Phase 3 SECURE Trial, a United States, multicenter, single-arm, open-label, 13-cycle trial that evaluated the efficacy, safety and tolerability of Twirla in 2,032 healthy women. Twirla is a combination of levonorgestrel and ethinyl estradiol indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m² for whom a combined hormonal contraceptive is appropriate.

The AGRX U.S. package insert also includes a Limitation of Use statement guiding prescribers to consider Twirla's reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². This post hoc analysis of SECURE assessed the efficacy, safety and tolerability of Twirla in women with BMI < 25 kg/m² and BMI 25-30 kg/m². When compared to women with BMI < 25 kg/m², Twirla demonstrated lower but acceptable efficacy while maintaining similar safety and tolerability in women with BMI 25-30 kg/m².

The results of this post hoc analysis help AGRX to inform providers counseling women that fall within BMI 25-30 kg/m² who may be considering a non-oral, noninvasive contraception option. These data support the safety and tolerability of Twirla in women within BMI 25-30 kg/m² as well as those with BMI < 25 kg/m²."

The AGRX Twirla product (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.

For more information on Agile Therapeutics (AGRX) visit www.agiletherapeutics.com

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