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

October 4, 2021
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(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 8.01. Other Events.

On October 4, 2021, Agile Therapeutics, Inc. (the "Company") issued a press release announcing that the California Medicaid Program, Medi-Cal, has placed the Company's Twirla® (levonorgestrel/ethinyl estradiol) transdermal system on the preferred drug formulary list as of October 1, 2021.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 4, 2021.
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: October 4, 2021

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

Exhibit 99.1

Agile Therapeutics Announces Addition of Twirla® to a Preferred Drug Position on Medi-Cal Formulary

Largest Medicaid program in the U.S. adds Twirla to Preferred Drug List as of October 1, 2021

PRINCETON, N.J., October 4, 2021 – Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, announced today that the California Medicaid Program, Medi-Cal, has placed Twirla on the preferred drug formulary list as of October 1, 2021. This development secures a preferred position for Twirla on the formulary for Medi-Cal and related programs which provide health care to approximately 15 million beneficiaries.

As of October 1, 2021, the preferred drug list placement for Medi-Cal will apply to those beneficiaries who receive their pharmacy benefit through fee-for-service (FFS) plans and related programs like the Family Planning, Access, Care and Treatment (Family PACT) Program, with the remainder of beneficiaries gaining access as of January 1, 2022.

“We continue to pursue expanding access to Twirla to as many women as possible. Broad access to as many contraceptive choices as possible, including the only contraceptive patch that delivers a low dose of estrogen, Twirla, allows a woman to select the contraceptive product that is right for her,” said Al Altomari, Chief Executive Officer of Agile Therapeutics, Inc. “We believe we have now taken an important step in that direction for women in California with the addition of Twirla to a preferred position on the formulary for Medi-Cal, the largest Medicaid program in the U.S.”

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^2 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^2 before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m^2. Twirla is 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), a 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.

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 placement on the preferred drug list of the California Medi-Cal formulary, our expansion of access to Twirla in California, our results of operations, revenues, financial condition, liquidity, prospects, growth and strategies, the expected benefits of our marketing and sales distribution strategies, including the use of samples to grow prescriptions, current and future Medicare coverage for Twirla, the development of our other potential product candidates, 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 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, 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 amounts 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. 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:
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