

Agile Therapeutics Announces \$7.8 Million Private Placement

March 4, 2019

PRINCETON, N.J., March 04, 2019 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's healthcare company, announced today that it has entered into a definitive stock purchase agreement with Perceptive Advisors, LLC, for the private placement of approximately 8.4 million shares of common stock at \$0.93 per share, resulting in expected gross proceeds of approximately \$7.8 million. The price per share is at least equal to the lower of (i) the closing price per share of our common stock (as reflected on Nasdaq.com) as of the close of the trading day immediately prior to the execution of the purchase agreement; or (ii) the average closing price per share of our common stock (as reflected on Nasdaq.com) for the five trading days immediately prior to the execution of the purchase agreement. The private placement is expected to close on or about March 4, 2019 subject to customary closing conditions.

"We are very pleased to have completed this private placement and with the vote of confidence from Perceptive," said Al Altomari, Chairman and Chief Executive Officer. "This financing provides us with the resources necessary to pursue approval of our lead product candidate, Twirla[®]."

Agile Therapeutics plans to use the net proceeds of the offering to fund working capital and general corporate purposes.

The securities issued in the private placement have not been registered under the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, these securities may not be reoffered or resold in the United States, except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act. This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

About Twirla[®] (AG200-15)

Twirla (levonorgestrel/ethinyl estradiol transdermal system) or AG200-15 is an investigational low-dose, once-weekly contraceptive patch. AG200-15 is a combined hormonal contraceptive ("CHC") patch that contains the active ingredients ethinyl estradiol ("EE"), a type of estrogen, and levonorgestrel ("LNG"), a type of progestin. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The Company has completed its Phase 3 clinical trials of Twirla and is pursuing regulatory approval in the U.S. Agile received a complete response letter ("CRL") from the FDA in December 2017 relating to the New Drug Application ("NDA") for Twirla. In the CRL, the FDA informed the Company that the product could not be approved in its present form due to deficiencies related to, among other things, the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. With the successful completion of the comparative wear study, the Company plans to resubmit the Twirla NDA in the second quarter of 2019.

About Agile Therapeutics, Inc.

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our 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 lead product candidate, Twirla[®] (levonorgestrel/ethinyl estradiol transdermal system), also known as AG200-15, is an investigational low-dose, 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 <u>www.agiletherapeutics.com</u>. The Company may occasionally disseminate material, nonpublic information on the Company's website.

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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, related to our regulatory submissions. 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 the expected gross proceeds and use of net proceeds of this private placement, and our ongoing and planned development, commercialization, and market update of Twirla. 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 forwardlooking statements are subject to risks and uncertainties including risks related to our ability to obtain additional funding, our ability to adequately and timely respond to the deficiencies in the second Twirla CRL issued by the FDA on December 21, 2017, the potential that the FDA determines that our data do not support resubmission or approval of Twirla NDA and requires us to conduct additional studies to address the concerns raised in the CRL. our ability to resubmit the Twirla NDA and obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain, our ability to obtain a favorable Advisory Committee vote in the likely event the FDA requires an Advisory Committee to review the benefit and risk profile of Twirla, our available cash and our ability to fund our business plan without delay and to continue as a going concern, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing, our third-party manufacturer, Corium International, Inc.'s ("Corium") inability to complete any work or provide any data and other information necessary to support the resubmission and approval of our Twirla NDA, our ability along with Corium to complete successfully the scale-up of the commercial manufacturing process for Twirla, including the qualification and validation of equipment related to the expansion of Corium's manufacturing facility and to pass a likely FDA pre-approval inspection, the performance and financial condition of Corium or any of the suppliers to our third-party manufacturer, the success and timing of our clinical trials or other studies, our ability to retain key employees, regulatory and legislative developments in the United States and foreign countries,

our plans to commercialize Twirla and develop our other potential product candidates, the size and growth of the potential markets for our product candidates and our ability to serve those markets, the rate and degree of market acceptance of any of our product candidates, our ability to obtain and maintain intellectual property protection for our product candidates, the successful development of our sales and marketing capabilities, our inability to timely obtain from our third-party manufacturer, Corium, sufficient quantities or quality of our product candidates or other materials required for a clinical trial or other tests and studies, our ability to successfully implement our strategy 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.

SOURCE: Agile Therapeutics, Inc.

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Agile Therapeutics

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Source: Agile Therapeutics, Inc.