Agile Therapeutics, Inc. Provides Corporate Update and Revised Cash Guidance

June 7, 2018

Cash Expected to Enable Company to Fund Operations into Second Quarter 2019

PRINCETON, N.J., June 07, 2018 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq:AGRX), a women's healthcare company, today announced several key corporate updates:

- Formal dispute resolution request has been submitted to the FDA regarding Twirla® (levonorgestrel/ethinyl estradiol transdermal system), its lead product candidate
- Reducing workforce by approximately 30% and reducing other planned expenses
- Reductions in workforce and expenses expected to allow existing cash to fund operations into the second quarter of 2019

Agile has submitted a formal dispute resolution request (FDRR) with the FDA for Twirla (AG200-15), the Company's investigational low-dose, non-daily, combination hormonal contraceptive patch. The dispute pertains to the determination from the FDA's reviewing Division of Bone, Reproductive and Urologic Products (DBRUP), that concerns surrounding the *in vivo* adhesion properties of Twirla prevent its approval and cannot be addressed through the Company's proposed patient compliance programs.

The Company anticipates that its FDRR will be reviewed by the Office of Drug Evaluation III (ODEIII) and has requested a meeting with the Office Director, which, according to FDA's guidance, should occur within thirty days of the request. After the meeting, the Director should provide a decision within thirty days.

The formal dispute resolution process exists to encourage open, prompt discussion of scientific and procedural disputes that arise during drug development, new drug review, and post-marketing oversight processes of the FDA. By submitting its FDRR, the Company is availing itself of the FDA's established appeal process whereby disagreements with conclusions reached by a reviewing Division within the FDA are reviewed above the Division level. Through this process the Company has the ability to escalate its appeal to additional levels of FDA management, if necessary.

"Twirla's adhesion profile was assessed in the context of a large Phase 3 trial, the objective of which was to demonstrate safety and efficacy as the basis for approval of the product. We continue to believe the objectives of this trial were met, and that there is no evidence that *in vivo* adhesion impacted the clinical outcomes of the trial. On this basis, we believe the *in vivo* adhesion data are adequate to support approval without the need for product reformulation or additional work. We have also developed multiple innovative approaches to patient compliance that we believe can further support or enhance the appropriate use of Twirla if it is approved," said Al Altomari, Chairman and Chief Executive Officer, Agile Therapeutics. "We disagree with the FDA's conclusions on the adhesion of Twirla and look forward to having the opportunity to engage with the Office of Drug Evaluation III on these issues."

The Company also announced a reduction in its workforce, which will result in the elimination of the positions of several employees primarily from the Company's commercial and clinical teams, representing approximately thirty percent of its employees. This workforce reduction, along with other reductions in its planned operating expenses, is designed to reduce operating expenses and preserve cash while the Company pursues formal dispute resolution. The Company now expects that its cash and cash equivalents as of March 31, 2018, will be sufficient to meet its operating requirements into the second quarter of 2019.

Mr. Altomari continued, "Due to the ongoing regulatory process with Twirla and our need to fund the formal dispute resolution process, we made the difficult decision to reduce our workforce. I would like to personally express my appreciation to each of the employees impacted by this decision for their commitment and contributions to Agile. We are also grateful to those members of our team that will continue to seek the approval of Twirla."

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. Agile received a complete response letter (CRL) from the FDA on December 21, 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 quality adhesion test methods, observations identified during the pre-approval inspection of the manufacturing facility for Twirla, and because of questions the FDA had on the *in vivo* adhesion properties of Twirla and their potential relationship to the Company's Phase 3 clinical trial results. As announced on May 18, 2018, Agile met with the FDA during a Type A meeting on April 16, 2018 to discuss the CRL and received the official end of review (EOR) minutes on May 15, 2018.

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) or 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 www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website.

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Forward-Looking Statement
Certain information contained in this press release includes "forward-looking statements" related to our regulatory submissions and projected cash position. 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 fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations beyond the second quarter of 2019, which raises substantial doubt about our ability to continue as a going concern, and which, in turn, may create negative reactions to the price of our common stock making it more difficult to obtain financing in the future, our ability to succeed in formal dispute resolution with the FDA, which can be lengthy and expensive and the success of which is not guaranteed and our belief that Twirla’s adhesion profile is adequate for approval and a reformulation of Twirla is not necessary. 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 manage costs and to execute on our operational and budget plans, our ability to either succeed in our formal dispute resolution with the FDA, or, if we are unsuccessful, our ability to develop a reformulation that will address the FDA’s concerns, if we are required to reformulate Twirla, our ability to successfully complete an additional adhesion study and bioequivalence study, the potential that we may be required to conduct an additional Phase 3 trial, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of our NDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, and unforeseen market factors or events in our clinical and manufacturing development plans and the other risks set forth 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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Source: Agile Therapeutics, Inc.