May 7, 2018

Agile Therapeutics Reports First Quarter 2018 Financial Results

Current Business Plan Expected to Enable Cash to Fund Operations through the end of 2018

PRINCETON, N.J., May 07, 2018 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's healthcare company, today reported financial results for the three months ended March 31, 2018 and provided a corporate update.

First quarter 2018 and other recent corporate developments include:

- **Twirla® Update** — As previously announced, on December 22, 2017, the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) in connection with its review of the New Drug Application (NDA) for the Company's investigational non-daily, low dose combination hormonal contraceptive patch, Twirla (AG200-15). The CRL informed the Company that the FDA could not approve the NDA in its present form due to deficiencies related to the manufacturing process for Twirla, and questions on the *in vivo* adhesion properties of Twirla and their potential relationship to the Phase 3 clinical trial results. At the Company's request, the FDA had a Type A meeting with the Company to discuss the deficiencies in the Twirla NDA and the potential regulatory path for approval of Twirla. The Company plans to provide an update on the outcome of the Type A meeting after it receives the official meeting minutes from the FDA and it will then be better able to determine when it will resubmit its Twirla NDA.

"We remain focused on working with the FDA to determine a potential path forward for the approval of Twirla," said Al Altomari, Chairman and Chief Executive Officer of Agile. "We believe that women continue to seek alternative contraceptive options that are convenient and that Twirla, if approved, will provide women with an important option they do not currently have, a contraceptive patch designed to deliver a low dose of estrogen."

First Quarter Financial Results

- **Cash and cash equivalents:** As of March 31, 2018, Agile had $28.3 million of cash and cash equivalents compared to $35.9 million of cash and cash equivalents as of December 31, 2017. In January 2018, in response to the 2017 CRL, the Company significantly scaled back equipment qualification and validation of its commercial manufacturing process and its other commercial pre-launch activities. Based on these actions and the Company's current business plan, the Company believes its cash and cash equivalents as of March 31, 2018, will be sufficient to meet its operating requirements through the end of 2018. The Company's current business plan assumes the resubmission of the Company's NDA for Twirla in the second quarter of 2018, a six-month FDA review of the NDA resubmission and resumption of both pre-launch commercial activities and pre-validation and validation of the commercial manufacturing process after Twirla approval, if the FDA approves Twirla. The Company will be better able to determine when it will submit its Twirla NDA once it receives the official minutes from the FDA from its Type A meeting. The Company will require additional capital to fund operating needs beyond 2018, including among other items, the completion of its commercial plan for Twirla, which primarily includes validation of the commercial manufacturing process and the commercial launch of Twirla, if approved, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were $4.0 million for the quarter ended March 31, 2018, compared to $4.7 million for the comparable period in 2017. The decrease in R&D expense was primarily due to decreased clinical development expenses as the Company's Phase 3 SECURE clinical trial for Twirla completed the close-out phase during 2017. The decrease in clinical development expenses was offset, in part, by increased expenses associated with commercial manufacturing scale-up activities.

- **General and administrative (G&A) expenses:** G&A expenses were $3.1 million for the quarter ended March 31, 2018, compared to $2.4 million for the comparable period in 2017. The increase in G&A expenses was primarily due to increased pre-commercialization activities, including personnel additions during the second half of 2017 to help prepare for launch of Twirla, if approved.

- **Net loss:** Net loss was $6.8 million, or $0.20 per share for the quarter ended March 31, 2018, compared to a net loss of $7.5 million, or $0.26 per share for the quarter ended March 31, 2017. Net loss for the quarter ended March 31, 2018 includes a benefit from income taxes of approximately $0.5 million, or $0.01 per basic share related to the sale of the Company's New Jersey net operation losses through the State of New Jersey's Technology Business Tax

Certificate Transfer Program (the "Program"). The Company has now reached the maximum lifetime benefit under the Program and will no longer be eligible to participate in the Program.

- **Shares Outstanding:** At March 31, 2018, Agile had 34,248,268 shares of common stock outstanding.

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®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch that has completed Phase 3 trials. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adhesion and patient wearability. For more information, please visit the company website at www.agiletherapeutics.com. We may occasionally disseminate material, nonpublic information on the company website.

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," "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. 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. Our statements about our ability to adequately and timely respond to the deficiencies in the CRL issued by the FDA in December 2017 may be affected by whether any such response will be accepted by the FDA, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, the possibility that the FDA may require additional studies to address the concerns raised in the CRL (for example, if it is determined that the product adhesion concerns raised in the CRL are due to the design or formulation of the drug product, the FDA may recommend that we design a new transdermal system and conduct another clinical trial with the new transdermal system in a U.S. population, or even if the FDA agrees with our position regarding the relationship between the *in vivo adhesion* properties of Twirla and the efficacy and safety results from our SECURE clinical trial, the FDA may still determine that the need for a convenient, contraceptive patch and the demonstrated efficacy of Twirla, including the pearl index from our SECURE clinical trial, do not outweigh the potential risks associated with the product, and therefore are not sufficient to support the approval of Twirla), or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA; our statements about the results of our clinical trial could be affected by the potential that there are changes in the interpretation of the data by the FDA (for example, the FDA continues to question the number of pregnancies included in our results and it may adjudicate additional pregnancies); our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute our operational and budget plans, if the FDA requires us to perform additional work or conduct additional studies prior to our resubmission of the NDA for Twirla, the fact that our existing cash and cash equivalents will not be sufficient to fund our current and planned operations beyond 2018, 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, and unforeseen events in our clinical and manufacturing development plans; our statements about the potential commercial opportunity could be affected by potential labeling restrictions, the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward-looking statements are subject to risks detailed 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. 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

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Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)

(Unaudited)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 28,344	$ 35,952
Prepaid expenses	633	762
Total current assets	28,977	36,714
Property and equipment, net	13,927	13,863
Other assets	18	18
Total assets	$ 42,922	$ 50,595
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,201	$ 3,636
Loan payable, current portion	9,090	10,607
Warrant liability	22	29
Total current liabilities	12,313	14,272
Loan payable, long-term	--	--
Total liabilities	12,313	14,272
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	259,211	258,092
Accumulated deficit	(228,605)	(221,772)
Total stockholders' equity	30,609	36,323
Total liabilities and stockholders' equity	$ 42,922	$ 50,595

Agile Therapeutics, Inc.
Condensed Statements of Operations

(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	$ 3,960	$ 4,721
General and administrative	3,086	2,405
Total operating expenses	7,046	7,126
Loss from operations	(7,046)	(7,126)
Other income (expense)		
Interest expense, net	(271)	(499)
Change in fair value of warrants	7	109
Loss before benefit from income taxes	(7,310)	(7,516)
Benefit from income taxes	477	—
Net loss	$ (6,833)	$ (7,516)
Net loss per share - basic and diluted	$ (0.20)	$ (0.26)
Weighted-average shares outstanding —basic and diluted	34,229,162	28,769,361