May 8, 2017

Agile Therapeutics Reports First Quarter 2017 Financial Results

Cash Expected to Fund Operations into Q2 2018

PRINCETON, N.J., May 08, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's healthcare company today reported financial results for the three months ended March 31, 2017, and provided a corporate update for the first quarter 2017.

First quarter 2017 and other recent corporate developments include:

- **Twirla® Update** — In January 2017, the Company announced positive top-line results from its Phase 3 SECURE clinical trial of Twirla®, its investigational low-dose combined hormonal contraceptive patch. SECURE was a multicenter, single-arm, open-label, 13 cycle trial that evaluated the safety, efficacy and tolerability of Twirla in 2,032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. In April 2017, the Company announced it had received the final meeting minutes from its recent New Drug Application (NDA) pre-submission meeting with the U.S. Food and Drug Administration (FDA) for Twirla. Based on the feedback from the FDA, the Company believes it has the necessary information needed to complete the resubmission of its NDA, which is expected to be submitted by the end of the second quarter of 2017.

- **Medical Congress Updates —** In March 2017, the Company announced a poster presentation of data from the Phase 3 SECURE clinical trial for Twirla. The poster, titled *"The SECURE Study, a Real-World Trial of a Low-Dose Contraceptive Patch: Addressing the Changing U.S. Population,"* was presented at the Contraceptive Technology Conferences in San Francisco, CA and Boston, MA. The first author is Anita Nelson, MD, one of the co-primary investigators for the SECURE trial. On April 29, 2017, Dr. Anita Nelson presented "*An Update on Hormonal Contraception and The Changing U.S. Population*" at the Academy of Women's Health, and on May 6, 2017, the Company also presented an interactive ePoster session during the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists. The ePoster included efficacy and safety findings for the overall population and pre-specified body mass index categories in the SECURE clinical trial. The ePoster also included results on the bleeding profile of subjects in the SECURE trial that have not previously been reported.

- **Hercules Loan and Security Agreement Amendment** — In May 2017, the Company amended its loan and security agreement with Hercules Capital, Inc. (Hercules) to extend the period during which the Company may draw an additional tranche of $8.5 million until January 31, 2018 subject to the consent of Hercules.

"During the first quarter, we continued to advance towards our goal of receiving regulatory approval for Twirla, participated in a productive pre-submission meeting with the FDA and continued to prepare our NDA for resubmission. Additionally we have had multiple scientific opportunities to discuss our Phase 3 SECURE trial results at medical conferences. We continue to expect to submit our NDA by the end of the second quarter of 2017," said Al Altomari, Chairman and Chief Executive Officer of Agile. "Additionally, we continue to focus on developing our commercialization plans in coordination with the prudent management of our capital resources. We believe that the flexibility built into our business plan can enable us to fund our operations into the second quarter of 2018."

First Quarter Financial Results

- **Cash and cash equivalents:** As of March 31, 2017, Agile had $41.7 million of cash and cash equivalents compared to $48.8 million of cash and cash equivalents as of December 31, 2016. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of March 31, 2017, will be sufficient to meet its operating requirements into the second quarter of 2018. The Company's current business plan assumes resubmission of the NDA for Twirla by the end of the second quarter of 2017, a six month FDA review of the Company's resubmission, initiation of pre-commercial activities and initiation of validation of its commercial manufacturing process in coordination with the commercialization of Twirla. The Company will require additional capital for the commercial launch of Twirla, if approved, as well as advancing the development of its other product candidates. In the event of unforeseen changes to its planned timelines, the Company has the ability to postpone certain commercial and validation spending that the Company believes will allow it to continue the funding of its operations into the second quarter of 2018.

- **Research and development (R&D) expenses:** R&D expenses were $4.7 million for the quarter ended March 31, 2017, compared to $4.9 million for the comparable period in 2016. 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 moved into the close-out phase. The decreased clinical development expenses were offset, in part, by expenses associated with commercial manufacturing scale-up activities.

- **General and administrative (G&A) expenses:** G&A expenses were $2.4 million for the quarter ended March 31, 2017, compared to $2.1 million for the comparable period in 2016. The increase in G&A expenses was primarily due to increased pre-commercialization activities.

- **Net loss:** Net loss was $7.5 million, or $0.26 per basic share for the quarter ended March 31, 2017, compared to a net loss of $7.3 million, or $0.27 per basic share for the quarter ended March 31, 2016.

- **Shares Outstanding:** At March 31, 2017, Agile had 28,776,398 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 recently 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. The company 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 the Company's clinical trials, regulatory submissions, projected cash position and potential market opportunity for its product candidates. 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 the results and conduct of our clinical trial could be affected by the potential that there are changes in the data or interpretation of the data by the FDA (for example, the FDA may include additional pregnancies in its calculation of the Pearl Index, which would increase the Pearl Index), whether the results will be deemed satisfactory by the FDA (for example, we describe the results of the SECURE trial as positive, the FDA may disagree with that characterization), and whether additional studies will be required or other issues will arise that will delay resubmission of our NDA or negatively impact acceptance, review and approval of Twirla by the FDA; our statements about our projected cash position could be affected by market factors, the inherent risks in our business, our ability to execute the Company's operational and budget plans, the FDA does not approve Twirla, the FDA's timeline for review is not completed within six months, our ability to timely complete the qualification and validation of our commercial manufacturing process, and unforeseen events in our clinical and manufacturing development plans; our statements about the potential commercial opportunity could be affected by 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 the Company's 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.

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	March 31, 2017	December 31, 2016

Assets		
Current assets:		
Cash and cash equivalents	$41,744	$48,750
Prepaid expenses	2,525	2,768
Total current assets	44,269	51,518
Property and equipment, net	12,330	12,330
Other assets	18	18
Total assets	$56,617	$63,866
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$5,749	$5,402
Loan payable, current portion	5,780	5,104
Warrant liability	63	172
Total current liabilities	11,592	10,678
Loan payable, long-term	9,416	10,899
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	236,590	235,754
Accumulated deficit	(200,984)	(193,468)
Total stockholders' equity	35,609	42,289
Total liabilities and stockholders' equity	$56,617	$63,866

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended March 31,	
	2017	**2016**
Operating expenses:		
Research and development	$4,721	$4,927
General and administrative	2,405	2,053
Total operating expenses	7,126	6,980
Loss from operations	(7,126)	(6,980)
Other income (expense)		
Interest expense, net	(499)	(531)
Change in fair value of warrants	109	193
Loss before benefit from income taxes	(7,516)	(7,318)
Benefit from income taxes	—	—
Net (loss) income	$(7,516)	$(7,318)
Net loss per share — basic and diluted	$(0.26)	$(0.27)
Weighted-average shares outstanding — basic and diluted	28,769,361	26,826,223

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