November 6, 2017

Agile Therapeutics Reports Third Quarter 2017 Financial Results

Cash Expected to Fund Operations into Q2 2018

Prescription Drug User Fee Act (PDUFA) Goal Date for Twirla® is December 26, 2017

PRINCETON, N.J., Nov. 06, 2017 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's healthcare company, today reported financial results for the three and nine months ended September 30, 2017, and provided a corporate update for the third quarter 2017.

Third quarter 2017 and other recent corporate developments include:

- **Twirla® Update** — On October 10, 2017, the Company hosted its first analyst day to present its corporate vision and commercial strategy for the potential launch of Twirla® (AG200-15), its investigational low-dose combined hormonal contraceptive patch product candidate. The Company also announced that the U.S. Patent and Trademark Office issued the Company four new patents with claims directed to novel transdermal contraceptive dosing regimens. These new patents provide an expanded proprietary platform not only for the development of Twirla and Agile's pipeline, but also for potential new products utilizing a broad selection of other progestins and estrogens.

- **Medical Congress Updates**
  - In September 2017, the Company announced that an abstract presenting data from the Phase 3 SECURE clinical trial of Twirla was selected for an oral presentation during the American Society of Reproductive Medicine (ASRM) Annual Congress which was held from October 28th to November 1st. The abstract, titled *"Selected Efficacy And Bleeding/Spotting Outcomes From The SECURE Trial: A Phase 3 Study of AG200-15, An Investigational Weekly Transdermal Contraceptive Patch"* is available in the September 2017 issue of Fertility and Sterility and online at www.fertstert.org.

  - In September 2017, the Company announced that an abstract based on the Phase 3 SECURE clinical trial of Twirla was selected for a poster presentation during the 2017 North American Forum on Family Planning which was held from October 14th to October 16th. The abstract, titled *"Bleeding And Spotting Results From The SECURE Trial: A Phase 3 Study of AG200-15 Investigational Transdermal Contraceptive Patch"* is available in the October 2017 issue of Contraception and online at www.contraceptionjournal.org.

- **Financing Update** — In August 2017, the Company completed an underwritten public offering of 5,333,334 shares of common stock at a public offering price of $3.75 per share. Proceeds from the offering, net of underwriting discounts, commissions and other offering costs were approximately $18.5 million and will be used to support commercialization activities for Twirla.

"This is an exciting time for the company as we continue preparing for the potential approval and commercialization of Twirla, our novel once-weekly contraceptive patch. If approved, Twirla would be the first low-dose non-daily alternative to an oral combined hormonal contraceptive introduced in over 15 years and represents a significant market opportunity," stated Al Altomari, Chairman and Chief Executive Officer of Agile. "We look forward to the potential growth opportunity ahead as we continue to execute on our strategic plans in preparation for our PDUFA goal date of December 26, 2017."

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2017, Agile had $43.8 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 September 30, 2017, will be sufficient to meet its operating requirements into the second quarter of 2018. The Company's current business plan assumes the FDA will complete its review of the Company's NDA resubmission by the target PDUFA goal date, December 26, 2017, initiation of certain pre-commercial activities prior to approval of Twirla and initiation and completion of validation of our commercial manufacturing process after the target PDUFA goal date, if the FDA approves Twirla. The Company will require additional capital to fund operating needs thereafter, including, among other items, continued commercial activities after the initial commercial launch for Twirla and advancing the development of our other product candidates. In the event of unforeseen changes to its planned timelines and business plan assumptions, as stated

above, the Company still believes it has the ability to continue funding its operations into the second quarter of 2018 by postponing certain planned commercial and validation spending.

- **Research and development (R&D) expenses:** R&D expenses were $3.2 million for the quarter ended September 30, 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 continued the close-out phase. The decrease in clinical development expenses was offset, in part, by increased expenses associated with commercial manufacturing scale-up activities, which we expect to continue to increase in 2017.

- **General and administrative (G&A) expenses:** G&A expenses were $3.5 million for the quarter ended September 30, 2017, compared to $2.2 million for the comparable period in 2016. The increase in G&A expenses was primarily due to increased pre-commercialization activities, which we expect to continue to increase in 2017.

- **Net loss:** Net loss was $7.1 million, or $0.22 per share for the quarter ended September 30, 2017, compared to a net loss of $7.8 million, or $0.27 per share for the quarter ended September 30, 2016.

- **Shares Outstanding:** At September 30, 2017, Agile had 34,158,004 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 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 by the target PDUFA goal date, our ability to timely complete the qualification and validation of our commercial manufacturing process, the fact that our existing cash and cash equivalents will not be sufficient to fund our current and planned operations through the next 12 months, 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; and 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.

Source: Agile Therapeutics

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Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 43,806	$ 48,750
Prepaid expenses	1,161	2,768
Total current assets	44,967	51,518
Property and equipment, net	13,426	12,330
Other assets	18	18
Total assets	$ 58,411	$ 63,866
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,680	$ 5,694
Loan payable, current portion	6,190	5,104
Warrant liability	90	172
Total current liabilities	10,960	10,970
Loan payable, long-term	5,887	10,607
Stockholders' equity		
Common stock	3	3
Additional paid-in capital	257,093	235,754
Accumulated deficit	(215,532)	(193,468)
Total stockholders' equity	41,564	42,289
Total liabilities and stockholders' equity	$ 58,411	$ 63,866

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 3,175	$ 4,911	$ 11,694	$ 15,415
General and administrative	3,526	2,180	9,130	6,497
Total operating expenses	6,701	7,091	20,824	21,912
Loss from operations	(6,701)	(7,091)	(20,824)	(21,912)
Other income (expense)				
Interest expense	(459)	(784)	(1,509)	(1,879)
Interest income	78	33	187	83
Change in fair value of warrants	(20)	38	82	168
Loss before benefit from income taxes	(7,102)	(7,804)	(22,064)	(23,540)
Benefit from income taxes	—	—	—	—
Net loss	$ (7,102)	$ (7,804)	$ (22,064)	$ (23,540)
Net loss per share — basic and diluted	$ (0.22)	$ (0.27)	$ (0.74)	$ (0.84)

Weighted-average shares outstanding — basic and diluted	31,937,628	28,754,458	29,847,972	28,110,587