Agile Therapeutics Reports Third Quarter 2019 Financial Results

October 28, 2019

FDA Advisory Committee Meeting for Twirla® NDA Scheduled for October 30, 2019

Cash Expected to Enable Company to Fund Operations through end of First Quarter 2020

PRINCETON, N.J., Oct. 28, 2019 (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, 2019 and provided a corporate update.

Third quarter 2019 and other recent corporate developments:

Twirla® Update

- *Regulatory update:* The FDA completed its pre-approval inspection (PAI) at Corium International, Inc. (Corium), our third-party manufacturer, and the Company continues its preparations for the October 30, 2019 meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) to review the Company's new drug application (NDA) for Twirla. The FDA has assigned the Twirla NDA a Prescription Drug User Fee Act (PDUFA) goal date of November 16, 2019. In advance of the Advisory Committee meeting, the FDA issued its briefing document in which it expresses a number of concerns regarding Twirla's approvability, including, but not limited to, concerns related to Twirla's efficacy when balanced against its safety. The FDA also did not appear to agree with the Company's proposal to include a limitation of use based on patient weight and BMI in the product label.

Public Offering

- *$12.7 Million in Net Proceeds From Sale of Common Stock:* The Company completed a public offering of 14,526,315 shares of common stock in August. Net proceeds from the public offering, after deducting underwriting discounts and commissions and offering expenses, were approximately $12.7 million.

Commercial Plans

- If the Company receives approval of the Twirla NDA, it plans to acclerate its commercial activities. In September 2019, the Company re-started manufacturing development at Corium. The Company is currently working with Corium to complete manufacturing development and process improvements and plans to commence pre-validation work when that work is complete. The Company's goal is to manufacture three validation batches of Twirla and complete the validation of the commercial manufacturing process in the second half of 2020.

- In parallel, the Company plans to initiate work with managed care and patient payers to gain market access for Twirla in the first quarter of 2020. In the second quarter of 2020, the Company plans to hire and train an initial sales team, which it estimates will be in the range of 50 to 90 persons. The Company expects to ship product to wholesalers and commence its commercial launch in fourth quarter of 2020. The Company's marketing efforts will initially focus on Obstetrician-gynecologists in the United States, and it plans to use a significant number of samples in the early stage of commercial launch to gain patient trial and acceptance.

"The third quarter of 2019 was another productive quarter for the Company" said Al Altomari, Chairman and Chief Executive Officer of Agile. "We raised much needed cash to fund our business and allow us to reactivate Corium to prepare for commercialization in the event that Twirla® is approved and to accomplish other precommercial activities. In addition, the FDA completed Corium's facility pre-inspection and our team has been preparing to present the case for NDA approval of Twirla® at the Advisory Committee meeting. We continue to believe that Twirla, if approved, will provide women with a new, important contraception option they do not currently have."

Third Quarter Financial Results

- **Cash and cash equivalents:** As of September 30, 2019, Agile had $18.4 million of cash and cash equivalents compared to $7.8 million of cash and cash equivalents as of December 31, 2018. During the quarter ended September 30, 2019, the Company raised net proceeds of approximately $12.7 million from a sale of 14,526,315 shares of common stock through a public offering in August and $0.2 million from the sale of 143,482 shares of common stock from its "at-the-market" equity offerings. The Company believes its cash and cash equivalents as of September 30, 2019 will be sufficient to meet its

projected operating requirements through the end of the first quarter 2020. The Company will require additional capital to fund operating needs for the rest of 2020 and beyond, which will primarily be used for the completion of its commercial plan for Twirla, if approved, including the completion of the validation of the commercial manufacturing process, the commercial launch, and advancing the development of its other potential product candidates.

- **Research and development (R&D) expenses:** R&D expenses were $2.4 million for the quarter ended September 30, 2019, compared to $1.5 million for the comparable period in 2018. The increase in R&D expenses was primarily related to consulting fees incurred in the preparation of the upcoming FDA Advisory Committee meeting. Partially offsetting this increase were decreases in manufacturing expense, commercialization expenses and stock compensation expense. The reduction in manufacturing and commercialization expenses reflects reduced activity associated with the scale-up of the commercial manufacturing process which was implemented as a result of the receipt of the 2017 CRL. The decrease in stock compensation expense was primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants.

- **General and administrative (G&A) expenses:** G&A expenses were $2.1 million for the quarter ended September 30, 2019, compared to $1.8 million for the comparable period in 2018. The increase in G&A expenses was primarily due to legal and finance costs, including investment banking advisory fees. Partially offsetting the increase was a decrease in stock compensation expense primarily the result of a lower stock price associated with the January 2019 stock option grants as compared to the January 2018 stock option grants and the suspension of pre-commercialization activities as a result of the receipt of the 2017 CRL.

- **Net loss:** Net loss was $4.4 million, or $0.08 per share, for the quarter ended September 30, 2019, compared to a net loss of $3.8 million, or $0.11 per share, for the quarter ended September 30, 2018.

- **Shares Outstanding:** At September 30, 2019, Agile had 59,302,126 shares of common stock outstanding.

About Twirla® (AG200-15)
Twirla (ethinyl estradiol and levonorgestrel transdermal system) or AG200-15 is an investigational low-dose, once-weekly 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. The Company resubmitted the Twirla NDA in the second quarter of 2019 and has been assigned a November 16, 2019 PDUFA goal date.

Xulane® is a registered trademark of Mylan N.V., and Ortho Evra® is a registered trademark of Johnson & Johnson.

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 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.

Forward-Looking Statement
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 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 approvability and subsequent availability of Twirla, the interpretation of data that supports the approval of Twirla, the timing of our advisory committee meeting and of the FDA's review of the Twirla NDA, and the fact that our existing cash and cash equivalents likely will not be sufficient to fund our current and planned operations after the end 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 expectations about Twirla and its NDA. 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 available cash and our ability to obtain additional funding to fund our business plan without delay and to continue as a going concern, our ability to adequately 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 approval of Twirla NDA and requires us to conduct additional studies or reformulate Twirla to address the concerns raised in the 2017 CRL, our ability to obtain and maintain regulatory approval of Twirla, our ability to obtain a favorable advisory committee vote regarding the benefit and risk profile of Twirla, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing, the inability of our third-party manufacturer, Corium International, Inc. (Corium), to complete any work or provide any data and other information necessary to support the 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 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, 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

Contact: Investor Relations -- 609-683-1880

Agile Therapeutics, Inc.
Condensed Balance Sheets

(in thousands)
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 18,370	$ 7,851
Prepaid expenses	1,316	607
Total current assets	19,686	8,458
Property and equipment, net	13,932	13,916
Right of use and other assets	214	18
Total assets	$ 33,832	$ 22,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,717	$ 2,218
Lease liability, current portion	178	-
Total current liabilities	1,895	2,218
Lease liability, long-term	34	-
Stockholders' equity		
Common stock	6	3
Additional paid-in capital	286,246	261,722
Accumulated deficit	(254,349)	(241,551)
Total stockholders' equity	31,903	20,174
Total liabilities and stockholders' equity	$ 33,832	$ 22,392

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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 2,361	$ 1,549	$ 7,021	$ 7,921
General and administrative	2,138	1,767	5,732	7,173
Restructuring costs	—	299	—	715
Total operating expenses	4,499	3,615	12,753	15,809
Loss from operations	(4,499)	(3,615)	(12,753)	(15,809)
Other income (expense)				
Interest expense	—	(268)	—	(955)
Interest income	67	91	168	289
Change in fair value of warrants	—	—	—	29
Loss before benefit from income taxes	(4,432)	(3,792)	(12,585)	(16,446)
Benefit from income taxes	—	—	—	477
Net loss	$ (4,432)	$ (3,792)	$ (12,585)	$ (15,969)

Net loss per share - basic and diluted	$ (0.08)	$ (0.11)	$ (0.28)	$ (0.47)
Weighted-average shares outstanding –basic and diluted	53,609,511	34,377,329	40,957,809	34,295,240

Source: Agile Therapeutics, Inc.