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Agile Therapeutics Reports Third Quarter 2014 Financial Results

Company Continues to Progress Clinical Trial Site Activation and Subject Enrollment

PRINCETON, N.J., Nov. 13, 2014 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc. (Nasdaq:AGRX), a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today reported financial results for the three and nine months ended September 30, 2014, and provided a Company update on activities related to its lead product candidate, Twirla® also known as AG200-15, a once-weekly prescription contraceptive patch currently in Phase 3 development.

Third quarter of 2014 and other recent highlights include:

- Continued to advance its Phase 3 SECURE Study, a single-arm, open-label, multicenter Phase 3 trial that will assess the efficacy, safety and tolerability of the Company's investigational once-weekly transdermal contraceptive patch, Twirla (AG200-15). The Company, in collaboration with Parexel International Corporation, its third party clinical research organization, made significant progress in the start-up of its Phase 3 SECURE study, with emphasis on site selection, training, and activation. Dosing of the initial patients commenced in September 2014, and approximately 50 of the planned 70 clinical sites were activated. The Company expects to complete patient enrollment by the end of the first quarter of 2015 and anticipates completing the trial at the end of the first quarter of 2016.
- Safety and tolerability data from the Company's previously completed randomized, controlled Phase 3 clinical trials of Twirla were accepted for publication by the *American Journal of Obstetrics and Gynecology* and published on-line in September 2014.
- Expanded its Board of Directors with the appointment of James P. Tursi, M.D., who currently serves as Chief Medical Officer for Auxilium Pharmaceuticals. As an experienced OB/GYN, Dr. Tursi brings significant clinical and regulatory expertise in the pharmaceutical industry to the board that the Company believes will prove beneficial in support of its clinical and regulatory strategies for Twirla.

"We continued to execute on our business plan during this quarter and made important progress on our key objectives. We advanced our confirmatory Phase 3 SECURE clinical program for Twirla and achieved a significant milestone with the commencement of patient dosing," said Al Altomari, President and Chief Executive Officer of Agile. "We remain on track with all the key elements of our operating plan and will continue to build on the positive momentum we have generated during this quarter."

Third Quarter Financial Results

As of September 30, 2014, Agile Therapeutics had cash and cash equivalents of \$45.7 million. Agile Therapeutics believes its current cash and cash equivalents are sufficient to fund operations through the first quarter of 2016.

For the third quarter of 2014, Agile Therapeutics reported a net loss of \$6.4 million, compared to a net loss of \$3.7 million for the comparable period in 2013.

Research and development expenses for the third quarter of 2014 were \$4.6 million, compared to \$2.4 million for the same period in 2013. The increase of \$2.2 million represents increased clinical development expenses, primarily CRO costs, associated with the Phase 3 clinical trial for Twirla.

General and administrative expenses for the third quarter of 2014 were \$1.4 million, compared to \$0.9 million for the same period in 2013. The increase of \$0.5 million was primarily due to increased professional fees and increased directors and officers insurance expense associated with becoming a public company.

About Agile

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options

that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. 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 adherence and patient acceptability. For more information, please visit the company website at www.agiletherapeutics.com.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's projected cash position, timeline for its clinical trials, and timeline for the qualification and validation of its commercial manufacturing process. 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 expectations 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. For example, our statements regarding 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, and unforeseen events in our clinical and manufacturing development plans; our statements about the timing and conduct of our clinical trial could be affected by the potential that we experience difficulty in enrolling subjects, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality, and the inherent risks of clinical development; our statements about the timeline for qualification and validation of our commercial manufacturing process could be affected by the potential that installation of the new equipment is more difficult than anticipated, Corium experiences delays with their suppliers and other vendors, Corium is unable to successfully manufacture product on a commercial scale according to our specifications and FDA regulations, Corium experiences regulatory enforcement actions related to their facility, and all the other risks inherent in developing and validating a commercial scale manufacturing process. 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 Registration Statement on Form S-1, and the prospectus filed in connection therewith and our Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as 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.

Balance Sheets

(Unaudited)

	<u>December 31, 2013</u>	<u>September 30, 2014</u>
Assets		
Current assets:		
Cash and cash equivalents	\$2,119,646	\$45,679,880
Prepaid expenses	146,704	1,369,494
Total current assets	2,266,350	47,049,374
Property and equipment, net of accumulated depreciation of \$273,092 in 2013 and \$280,823 in 2014	11,963,079	11,997,697
Deferred financing costs, net	157,499	115,693
Prepaid expenses, long-term	--	1,677,434
Other assets	18,208	18,208
Total assets	<u>\$14,405,136</u>	<u>\$60,858,406</u>
Liabilities, convertible preferred stock and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$715,454	\$2,654,871
Accrued expenses	379,164	660,139
Loan payable, current portion	5,105,407	3,559,743
Warrant liability	644,478	365,914
Total current liabilities	6,844,503	7,240,667
Loan payable, long-term	9,769,528	11,241,442

Commitment and contingencies

Series A-1, 8%, non-cumulative convertible preferred stock, \$.0001 par value, authorized 284,743 shares; issued and outstanding 137,787 shares at December 31, 2013 and 0 shares at September 30, 2014	898,305	--
Series A-2 convertible preferred stock, \$.0001 par value, authorized 99,178 shares; issued and outstanding 66,116 shares at December 31, 2013 and 0 shares at September 30, 2014	543,623	--
Series B, 8% non-cumulative, convertible preferred stock, \$.0001 par value, authorized 4,510,066 shares; issued and outstanding 4,510,066 shares at December 31, 2013 and 0 shares at September 30, 2014	44,928,382	--
Series C, 12% non-cumulative, convertible preferred stock, \$.0001 par value, authorized 2,711,734 shares; issued and outstanding 1,578,400 at December 31, 2013 and 0 shares at September 30, 2014	22,862,367	--
Stockholders' (deficit) equity:		
Preferred stock, \$.0001 par value, authorized 10,000,000 shares; issued 0 shares outstanding at December 31, 2013 and September 30, 2014	--	--
Common stock, \$.0001 par value, authorized 150,000,000 shares; issued 109,321 and outstanding 103,536 shares at December 31, 2013 and issued 18,598,754 and outstanding 18,592,968 shares at September 30, 2014	88	1,860
Additional paid-in capital	46,872,723	169,921,290
Accumulated deficit	<u>(118,314,383)</u>	<u>(127,546,853)</u>
Total stockholders' (deficit) equity	<u>(71,441,572)</u>	<u>42,376,297</u>
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	<u>\$14,405,136</u>	<u>\$60,858,406</u>

Agile Therapeutics, Inc.
Statements of Operations

(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2013</u>	<u>2014</u>	<u>2013</u>	<u>2014</u>
Operating expenses:				
Research and development	\$ 2,397,898	\$ 4,602,513	\$ 7,895,352	\$ 8,387,693
General and administrative	923,491	1,446,371	2,903,468	3,603,528
Total operating expenses	<u>3,321,389</u>	<u>6,048,884</u>	<u>10,798,820</u>	<u>11,991,221</u>
Loss from operations	(3,321,389)	(6,048,884)	(10,798,820)	(11,991,221)
Other income (expense)				
Interest expense	(378,228)	(392,009)	(1,134,684)	(1,173,723)
Interest income	152	1,288	1,584	1,425
Change in fair value of warrants	8,510	86,243	24,856	278,564
Loss before benefit from income taxes	<u>(3,690,955)</u>	<u>(6,353,362)</u>	<u>(11,907,064)</u>	<u>(12,884,955)</u>
Benefit from income taxes	—	—	—	3,652,485
Net loss	<u>\$ (3,690,955)</u>	<u>\$ (6,353,362)</u>	<u>\$ (11,907,064)</u>	<u>\$ (9,232,470)</u>
Net loss per common share:				
Basic and Diluted	<u>\$ (71.67)</u>	<u>\$ (0.34)</u>	<u>\$ (245.88)</u>	<u>\$ (1.03)</u>
Weighted-average shares outstanding:				
Basic and Diluted	<u>51,499</u>	<u>18,592,968</u>	<u>48,427</u>	<u>8,967,324</u>

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