



August 14, 2014

## **Agile Therapeutics Reports Second Quarter 2014 Financial Results**

### **Company on Track With Initiation of Confirmatory Phase 3 Clinical Trial of Twirla(TM) in Third Quarter of 2014**

PRINCETON, N.J., Aug. 14, 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 six months ended June 30, 2014, and provided a Company update on activities related to its lead product candidate, [Twirla](#)<sup>TM</sup>, also known as AG2005, a once-weekly prescription contraceptive patch currently in Phase 3 development.

"The second quarter was an exciting time of growth and activity for Agile. We successfully completed our initial public offering in May, and now we are financially positioned to advance our lead product Twirla through the Phase 3 clinic," said Al Altomari, President and Chief Executive Officer of Agile. "Our primary focus continues to be on the successful execution of our confirmatory Phase 3 study for Twirla which is on track to begin enrollment in this quarter."

#### **Second Quarter Financial Results**

As of June 30, 2014, Agile Therapeutics had cash and cash equivalents of \$53.5 million. In May 2014, the Company completed its initial public offering (IPO) of common stock, raising net proceeds of approximately \$49.7 million. Agile Therapeutics believes its current cash and cash equivalents are sufficient to fund operations through the first quarter of 2016.

For the second quarter of 2014, Agile Therapeutics reported a net loss of \$3.7 million, compared to a net loss of \$3.6 million for the comparable period in 2013.

Research and development expenses for both the second quarters of 2014 and 2013 were \$2.4 million.

General and administrative expenses for the second quarter of 2014 were \$1.1 million, compared to \$0.8 million for the same period in 2013. The increase of \$0.3 million was primarily due to increased professional fees associated with being a public company.

#### **First Half Financial Results**

For the six months ended June 30, 2014, Agile Therapeutics reported a net loss of \$2.9 million, compared to a net loss of \$8.2 million for the comparable period in 2013.

Research and development expenses for the six months ended June 30, 2014 were \$3.8 million, compared to \$5.5 million for the same period in 2013. The decrease of \$1.7 million was primarily due to decreased regulatory consulting fees and manufacturing commercialization expenses, offset, in part, by an increase in clinical development expenses related to start-up activities for the confirmatory Phase 3 clinical trial for Twirla.

General and administrative expenses for the six months ended June 30, 2014 were \$2.2 million, compared to \$2.0 million for the same period in 2013. The increase of \$0.2 million was primarily due to increased professional fees associated with being a public company.

Agile Therapeutics recorded a tax benefit of \$3.6 million for the six months ended June 30, 2014, reflecting the proceeds received from the sale of a portion of the Company's New Jersey net operating losses.

#### **Company Update**

During the second quarter of 2014, the Company continued to advance its business in three key areas: initiating its confirmatory Phase 3 clinical trial of its product candidate Twirla, collaborating with Corium International (Corium), its third party manufacturer, to prepare clinical supply and plan the commercial scale up of manufacturing capabilities, and expanding its intellectual property portfolio.

The Company, in collaboration with Parexel International Corporation, its third party clinical research organization, made progress in the start-up of its confirmatory Phase 3 clinical trial, focusing on site selection and training activities. The Company also selected PHT Corporation as its partner to provide e-diaries for the trial. As previously disclosed, the Company expects to enroll its first subject in the trial in the third quarter 2014. The Company also expects that it is likely to complete the trial in the first quarter of 2016. The Company believes the key drivers of the timing for completion of the trial are the timelines for clinical supply and the pace of site selection, site initiation and subject enrollment.

The Company also continued to work closely with Corium to prepare clinical supply of its product candidate, Twirla, for the confirmatory Phase 3 clinical trial. The Company is currently planning the commercial scale up of manufacturing capabilities for Twirla, and is collaborating with Corium to continue the qualification and validation of equipment related to the expansion of Corium's commercial manufacturing capabilities. The Company expects to complete the validation and expansion by the end of 2016, in coordination with its planned commercialization activities. Corium is responsible for all aspects of Twirla manufacturing.

During the second quarter of 2014, the Company advanced its efforts to expand its intellectual property portfolio covering its [Skinfusion](#)<sup>®</sup> transdermal technology. In June, the Company announced that patent 8,747,888, a continuation of its prior patent 8,246,978, was issued in the U.S. and is intended to provide additional patent protection covering the transdermal contraceptive patch system for its product candidate Twirla. In July, the Company announced that it received a notice of allowance in the U.S. for additional claims covering dosing regimens using Twirla. The Company expects to list seven patents in the U.S. FDA's Orange Book, if its product candidate, Twirla, is approved. The Company has multiple additional applications on file in the U.S. and internationally relating to further advances in the Skinfusion transdermal delivery system.

## 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<sup>®</sup>, 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](http://www.agiletherapeutics.com).

## Forward Looking Statements

Certain information contained in this press release includes "forward-looking statements" related to the Company's projected cash position, timeline for its clinical trials, timeline for the qualification and validation of its commercial manufacturing process, and listing of patents in the U.S. FDA Orange Book. 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 identifying and initiating sites and 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 supplied in a timely fashion, 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's 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; our statements about listing patents in the U.S. FDA's Orange Book could be affected by the potential that Twirla does not receive regulatory approval, the listing of the patents is challenged and the Company is required to remove a patent from the Orange Book, and all the other risks inherent to intellectual property. 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 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.**

**Balance Sheets**

**(Unaudited)**

	December 31, 2013	June 30, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$2,119,646	\$53,494,022
Prepaid expenses and other current assets	146,704	661,218
Total current assets	2,266,350	54,155,240
Property and equipment, net of accumulated depreciation of \$273,092 in 2013 and \$278,135 in 2014	11,963,079	11,964,777
Deferred financing costs, net	157,499	132,985
Other assets	18,208	18,208
Total assets	<u>\$14,405,136</u>	<u>\$66,271,210</u>
<b>Liabilities, convertible preferred stock and stockholders' (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$715,454	\$2,325,664
Accrued expenses	379,164	373,270
Loan payable, current portion	5,105,407	2,151,653
Warrant liability	644,478	452,157
Total current liabilities	6,844,503	5,302,744
Loan payable, long-term	9,769,528	12,619,816
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 June 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 June 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 June 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 June 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 June 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 June 30, 2014	88	1,860
Additional paid-in capital	46,872,723	169,540,281
Accumulated deficit	(118,314,383)	(121,193,491)
Total stockholders' (deficit) equity	(71,441,572)	48,348,650
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	<u>\$14,405,136</u>	<u>\$66,271,210</u>

**Agile Therapeutics, Inc.**  
**Statements of Operations**  
**(Unaudited)**

	Three Months Ended June 30, 2013	2014	Six Months Ended June 30, 2013	2014
Operating expenses:				
Research and development	\$ 2,425,741	\$ 2,390,857	\$ 5,497,454	\$ 3,785,180
General and administrative	823,329	1,103,853	1,979,977	2,157,157
Total operating expenses	<u>3,249,070</u>	<u>3,494,710</u>	<u>7,477,431</u>	<u>5,942,337</u>

Loss from operations	(3,249,070)	(3,494,710)	(7,477,431)	(5,942,337)
Other income (expense)				
Interest expense	(378,228)	(403,488)	(756,456)	(781,714)
Interest income	259	82	1,432	137
Change in fair value of warrants	<u>7,160</u>	<u>179,715</u>	<u>16,346</u>	<u>192,321</u>
Loss before benefit from income taxes	<u>(3,619,879)</u>	<u>(3,718,401)</u>	<u>(8,216,109)</u>	<u>(6,531,593)</u>
Benefit from income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>3,652,485</u>
Net loss	<u>\$ (3,619,879)</u>	<u>\$ (3,718,401)</u>	<u>\$ (8,216,109)</u>	<u>\$ (2,879,108)</u>
Net loss per common share:				
Basic and Diluted	<u>\$ (70.29)</u>	<u>\$ (0.46)</u>	<u>\$ (175.31)</u>	<u>\$ (0.71)</u>
Weighted-average shares outstanding:				
Basic and Diluted	<u>51,499</u>	<u>8,000,092</u>	<u>46,865</u>	<u>4,074,734</u>
Unaudited pro forma net loss		<u>\$ (3,697,734)</u>		<u>\$ (2,858,441)</u>
Unaudited pro forma net loss per share (1)		<u>\$ (0.28)</u>		<u>\$ (0.26)</u>
Unaudited pro forma weighted average basic and diluted common shares outstanding (1)		<u>13,197,576</u>		<u>11,068,161</u>

(1) Assumes the conversion of all outstanding shares of convertible preferred stock and convertible promissory notes into shares of common stock as of the beginning of the period or the date of issuance and related adjustment to eliminate interest expense on the promissory notes.

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Source: Agile Therapeutics

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