



August 13, 2015

Agile Therapeutics Reports Second Quarter Financial Results

Continues to Progress Clinical Trial; Patents for Proprietary Platform to Develop New Women's Contraceptive Products Allowed

PRINCETON, N.J., Aug. 13, 2015 (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, 2015 and provided a corporate update for the second quarter 2015.

Second quarter 2015 and other recent corporate developments include:

- In June 2015, the Company was granted US Patent 9,050,348 which includes claims directed to the peripheral adhesive system used in the Company's lead product candidate Twirla[®] (ethinyl estradiol and levonorgestrel transdermal system) currently in Phase 3 development. The patent includes claims that relate to the enhanced adhesion characteristics of the Twirla[®] patch combined with its low rates of skin irritation.
- In June 2015, the Company was selected for addition to the U.S. Russell 2000[®], Russell 3000[®] and Russell Global Indexes as part of the 2015 Russell indexes reconstitution.
- In July 2015, the Company received notice that the U.S. Patent and Trademark Office issued Notices of Allowance for four patent applications with claims directed to novel transdermal contraceptive dosing regimens. The allowances of these patent applications provides the Company with an additional proprietary platform for the development of new products based on the Company's lead product candidate Twirla.

"During the second quarter, we advanced our strategy for providing women additional contraceptive choices," said Al Altomari, Chief Executive Officer and President of Agile. "We continued to execute on our near-term strategy and are pleased with our progress towards completing enrollment in our Twirla Phase III SECURE clinical trial by the end of the third quarter. We also broadened our intellectual property portfolio with the allowance of several important patent applications that can provide us with a platform for developing new pipeline products beyond Twirla and position us for potential longer term growth."

Second Quarter Financial Results

- **Cash and cash equivalents:** As of June 30, 2015, Agile had \$46.4 million of cash and cash equivalents compared to \$40.2 million of cash and cash equivalents as of December 31, 2014. Based on our current business plan, Agile believes its cash and cash equivalents will be sufficient to meet its operating requirements through the end of 2016. In addition to its existing cash and cash equivalents, upon the achievement of certain clinical milestones, the Company would be eligible to draw an additional tranche of \$8.5 million under the terms of the loan and security agreement with Hercules Technology Growth Capital, Inc.
- **Research and development (R&D) expenses:** R&D expenses were \$6.2 million for the quarter ended June 30, 2015, compared to \$2.4 million for the comparable period in 2014. The increase in R&D expense of \$3.8 million was primarily due to CRO costs associated with the ongoing Phase 3 clinical trial for Twirla.
- **General and administrative (G&A) expenses:** G&A expenses were \$1.8 million for the quarter ended June 30, 2015, compared to \$1.1 million for the comparable period in 2014. The increase in G&A expenses of \$0.7 million was primarily due to increased compensation expense related to an increase in headcount, increased stock-based compensation expense and increased directors' and officers' insurance expense to support public company operations.
- **Net loss:** Net loss was \$8.5 million, or \$0.38 per basic share for the quarter ended June 30, 2015, compared to a net loss of \$3.7 million, or \$0.46 per basic share for the quarter June 30, 2014.
- **Shares Outstanding:** At June 30, 2015, Agile had 22,238,137 shares of common stock outstanding.

About Agile Therapeutics, Inc.

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. 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, projected cash position, timeline for clinical trials 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 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 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, 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 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)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$46,408	\$40,182
Prepaid expenses	817	804
Total current assets	47,225	40,986
Property and equipment, net	12,310	12,046
Other assets, long-term	2,140	1,794
Total assets	\$61,675	\$54,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$4,878	\$3,693
Loan payable, current portion	---	5,003
Warrant liability	356	296
Total current liabilities	5,234	8,992
Loan payable, long-term	15,258	9,828

Stockholders' equity

Common stock	2	2
Additional paid-in capital	192,598	170,396
Accumulated deficit	<u>(151,417)</u>	<u>(134,392)</u>
Total stockholders' equity	<u>41,183</u>	<u>36,006</u>
Total liabilities and stockholders' equity	<u><u>\$61,675</u></u>	<u><u>\$54,826</u></u>

Agile Therapeutics, Inc.
Condensed Statements of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 6,168	\$ 2,391	\$ 11,546	\$ 3,785
General and administrative	<u>1,813</u>	<u>1,104</u>	<u>3,413</u>	<u>2,157</u>
Total operating expenses	<u>7,981</u>	<u>3,495</u>	<u>14,959</u>	<u>5,942</u>
Loss from operations	(7,981)	(3,495)	(14,959)	(5,942)
Interest expense, net	(546)	(403)	(971)	(782)
Change in fair value of warrants	41	180	(59)	192
Loss on extinguishment of debt	<u>--</u>	<u>--</u>	<u>(1,036)</u>	<u>--</u>
Loss before benefit from income taxes	<u>(8,486)</u>	<u>(3,718)</u>	<u>(17,025)</u>	<u>(6,532)</u>
Benefit from income taxes	<u>--</u>	<u>--</u>	<u>--</u>	<u>3,652</u>
Net loss	<u><u>\$ (8,486)</u></u>	<u><u>\$ (3,718)</u></u>	<u><u>\$ (17,025)</u></u>	<u><u>\$ (2,879)</u></u>
Net loss per common share:				
Basic and Diluted	<u><u>\$ (0.38)</u></u>	<u><u>\$ (0.46)</u></u>	<u><u>\$ (0.78)</u></u>	<u><u>\$ (0.71)</u></u>
Weighted-average shares outstanding:				
Basic and Diluted	<u><u>22,202,680</u></u>	<u><u>8,000,092</u></u>	<u><u>21,745,318</u></u>	<u><u>4,074,734</u></u>

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Source: Agile Therapeutics

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