

AGILE THERAPEUTICS INC
Form 10-Q
August 14, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2014

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 001-36464

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

23-2936302

(I.R.S. Employer Identification No.)

101 Poor Farm Road

Princeton, New Jersey 08540

(Address including zip code of principal executive offices)

(609) 683-1880

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if smaller reporting company)

Smaller reporting company

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

There were 18,592,968 shares of the registrant's common stock, \$0.0001 par value, outstanding as of August 13, 2014.

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Agile Therapeutics, Inc.
Quarterly Report On Form 10-Q
For The Quarter Ended June 30, 2014

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes statements that are, or may be deemed, forward-looking statements. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, plans, intends, may, could, might, will, should, approximately or, in each case, their negative or other variations thereof, terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-Q and include statements regarding our current intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned development of Twirla and our other product candidates, the strength and breadth of our intellectual property, our ongoing and planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our development and validation of manufacturing capabilities, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-Q, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials;
 - 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;
 - our ability along with Corium to complete successfully the qualification and validation of equipment related to the expansion of Corium's manufacturing facility;
 - our ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
 - our plans to develop and commercialize our product candidates;
 - the size and growth of the potential markets for our product candidates and our ability to serve those markets;
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- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- our available cash;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the performance of third-party manufacturers; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the Risk Factors section of this Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Table of Contents**Agile Therapeutics, Inc.****Part I Financial Information****Item 1. Financial Statements****Agile Therapeutics, Inc.****Balance Sheets****(Unaudited)**

	December 31, 2013	June 30, 2014
Assets		
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	\$ 14,405,136	\$ 66,271,210
Liabilities, convertible preferred stock and stockholders (deficit) equity		
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:		

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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	\$	14,405,136	\$ 66,271,210

See accompanying notes to unaudited financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	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	3,249,070	3,494,710	7,477,431	5,942,337
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	7,160	179,715	16,346	192,321
Loss before benefit from income taxes	(3,619,879)	(3,718,401)	(8,216,109)	(6,531,593)
Benefit from income taxes				3,652,485
Net loss	\$ (3,619,879)	\$ (3,718,401)	\$ (8,216,109)	\$ (2,879,108)