

May 15, 2019



Achieve Reports Financial Results for First Quarter 2019 and Provides Cytisinicline Clinical Development Update

SEATTLE and VANCOUVER, British Columbia, May 15, 2019 /CNW/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today provided an update on the cytisinicline clinical development program and announced first quarter 2019 financial results.



ORCA-1 Trial Status

Achieve's 254-subject Phase 2b ORCA-1 trial of cytisinicline in U.S. smokers completed enrollment in February. The Company announced recently that the last study visit for the last subject enrolled in the ORCA-1 trial has occurred. The trial is evaluating cytisinicline in both the 1.5 mg and 3.0 mg doses on a declining titration schedule as well as three times daily dosing, both over 25 days. The primary efficacy endpoint is reduction in the number of cigarettes smoked during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 topline efficacy and safety data are expected to be announced by the end of the second quarter.

Maximum Tolerated Dose (MTD) Trial Extension

Achieve recently initiated a trial to assess the MTD for a single administered oral dose of cytisinicline in smokers. The starting dosage of cytisinicline was 6 mg and is increased in separate groups of subjects for each escalated dose level until stopping criteria, based on the occurrence of dose-limiting adverse events, are reached. To date, 21 mg cytisinicline has been evaluated without evidence of dose limiting toxicity. The trial's Data Safety Monitoring Committee has recommended a protocol amendment to evaluate additional higher doses of cytisinicline.

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, "With the results of the ORCA-1 trial expected by the end of the second quarter, we are rapidly approaching another critical milestone for the cytisinicline development program. Importantly, as confirmed by the tolerability of high dose levels in our MTD study, we believe cytisinicline may offer a differentiated and new treatment option for the millions of people who are battling nicotine addiction."

Financial Results

As of March 31, 2019, the company's cash, cash equivalents, short-term investments and restricted cash were \$9.7 million. Each of total operating expenses and net loss for the first quarter of 2019 were \$5.9 million.

As of May 15, 2019 Achieve had 6,865,950 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 p.m. Eastern time today, Wednesday, May 15, 2019. To access the webcast, log on to the investor relations page of the Achieve website at <http://ir.achievelifesciences.com/events-and-webcasts>. Alternatively, access to the live conference call is available by dialing (877) 472-9809 (U.S. & Canada) or (629) 228-0791 (International) and referencing conference ID 6973659. A webcast replay will be available approximately two hours after the call and will be archived on the website for 90 days.

About Achieve and Cytisinicline

Tobacco use is currently the leading cause of preventable death and is responsible for nearly seven million deaths annually worldwide¹. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking². Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisinicline.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the planned cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, expectations from current data, expectations regarding when trial data may be reported, the potential market size for cytisinicline and the potential benefits of cytisinicline. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that Achieve may not be able to obtain additional financing to fund the development of cytisinicline; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that Achieve's intellectual property may not be adequately protected; general business and economic conditions; and the other factors described in the risk factors set forth in Achieve's filings with the Securities and Exchange Commission from time to time, including Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable.

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"ORCA is a trademark of Achieve Life Sciences, Inc."

¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2017. Geneva: World Health Organization, 2017

² Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

Consolidated Statements of Loss
(In thousands, except per share and share data)

		<u>Three months ended March 31,</u>	
		<u>2019</u>	<u>2018</u>

Operating expenses:

Research and development	4,055	1,201
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General and administrative	1,885	1,813
Total operating expenses	5,940	3,014
Loss from operations	(5,940)	(3,014)
Other income (expense)	36	(8)
Net loss	<u>\$ (5,904)</u>	<u>\$ (3,022)</u>
Basic and diluted net loss per share	<u>\$ (0.88)</u>	<u>\$ (2.43)</u>
Weighted average number of basic and diluted common shares	<u>6,721,184</u>	<u>1,243,149</u>

Consolidated Balance Sheets
(In thousands)

	March 31, 2019	December 31, 2018
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 9,715	\$ 14,654
Prepaid expenses and other current assets	866	933
Property, equipment and other assets	177	153
Operating lease right-of-use assets	455	—
License agreement	2,254	2,310
Goodwill	1,034	1,034
Total assets	<u>\$ 14,501</u>	<u>\$ 19,084</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 3,813	\$ 3,259
Current portion of long-term obligations	16	11
Current portion of long-term lease liability	170	—
Long-term obligations	24	12
Long-term lease liability	289	—
Stockholders' equity	<u>10,189</u>	<u>15,802</u>
Total liabilities and stockholders' equity	<u>\$ 14,501</u>	<u>\$ 19,084</u>

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