

May 14, 2020

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Achieve Reports Financial Results for First Quarter 2020 and Provides Update on Cytisinicline Development Program

SEATTLE and VANCOUVER, British Columbia, May 14, 2020 /CNW/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced first quarter 2020 financial results and provided an update on the cytisinicline clinical development program.



Recent Highlights

- Submitted required non-clinical supportive data for longer cytisinicline treatment to the U.S. Food & Drug Administration (FDA) in preparation for Phase 3 cytisinicline ORCA-2 trial initiation
- Closed financing for gross proceeds of approximately \$1.9 million, prior to deducting placement agent commissions and estimated offering expenses
- Presented new findings from the Phase 2b ORCA-1 trial evaluating cytisinicline in U.S. smokers at the Society for Research on Nicotine & Tobacco (SRNT) Annual Conference

- Established agreement with the FreeMind Group to assist in securing non-dilutive funding to evaluate cytisinicline in vapers and e-cigarette users

"The COVID-19 pandemic has revealed an increased risk for smokers due to the known relationship between smoking and respiratory illnesses and we see an even greater need to do all that we can to help them quit," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. "We expect to initiate the 750 patient Phase 3 ORCA-2 trial in the second-half of 2020, subject to financing and the ability to conduct the trial safely in light of the COVID-19 pandemic."

Completed FDA Submission

In preparation for initiation of the Phase 3 ORCA-2 clinical trial of cytisinicline, the Company has now submitted to FDA all requested non-clinical data to allow 6 and 12 weeks of cytisinicline treatment in the Phase 3 trials. No new safety or toxicology signals were observed in the non-clinical data evaluating either 13 or 26 weeks of cytisinicline treatment.

Closed private placement financing for gross proceeds of \$1.9 million

In April 2020, Achieve announced it entered into definitive agreements for a private placement of its securities for gross proceeds of approximately \$1.9 million, prior to deducting placement agent commissions and estimated offering expenses. The Company intends to use the proceeds to fund clinical research and development, and for general working capital.

Additional ORCA-1 Results at SRNT Annual Conference

An oral presentation featuring new ORCA-1 Phase 2b trial analyses was presented at the SRNT Annual Meeting in March 2020. In addition to previously reported data indicating a statistically significant improvement in quit rates, new analyses demonstrate cytisinicline biochemical efficacy via measurement of serum cotinine as well as the previous carbon monoxide efficacy. Additionally, further analyses confirm that cytisinicline benefit was observed across all clinical sites, baseline characteristics, and attributes. Thus, regardless of trial site location, patient demographics, smoking history, or prior treatments, all subjects treated with cytisinicline showed similar smoking cessation benefit.

Agreement with the FreeMind Group to secure non-dilutive financing for vaping trials

In the first quarter of 2020, Achieve retained the FreeMind Group, an international consulting firm dedicated to assisting life science organizations secure non-dilutive funding. Achieve and FreeMind are conducting a strategic assessment of potential non-dilutive funding opportunities from various public and private sources, followed by anticipated grant production and submission, to further the clinical development of cytisinicline in vaping or e-cigarette cessation.

Financial Results

As of March 31, 2020, the company's cash, cash equivalents, and restricted cash was \$12.2 million. Total operating expenses for the quarter ended March 31, 2020 were \$3.4 million. Total net loss for the quarter ended March 31, 2020 was \$3.3 million.

As of March 14, 2020, Achieve had 37,515,408 shares outstanding.

Conference Call Details

Achieve will host a conference call at 8:00 a.m. Eastern time today, Thursday, May 14,

2020. 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 4477265. 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 more than eight 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 and nicotine addiction 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 ability to secure any non-dilutive financing, the timing and nature of cytisinicline clinical development activities, the potential market size for cytisinicline, the potential benefits of cytisinicline, the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, and the development and effectiveness of new treatments. 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; risks related to the impact on our business of the COVID-19 pandemic or similar public health crises 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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¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. 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)

	Three months ended March 31,	
	2020	2019
Operating expenses:		
Research and development	1,541	4,055
General and administrative	1,816	1,885
Total operating expenses	3,357	5,940
Loss from operations	(3,357)	(5,940)
Other income (expense)	37	36
Net loss	<u>\$ (3,320)</u>	<u>\$ (5,904)</u>
Basic and diluted net loss per share	<u>\$ (0.11)</u>	<u>\$ (0.88)</u>
Weighted average number of basic and diluted common shares	<u>30,936,777</u>	<u>6,721,184</u>

Consolidated Balance Sheets (In thousands)

	March 31,	December 31,
	2020	2019
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 12,206	\$ 16,714
Prepaid expenses and other current assets	746	670
Property, equipment and other assets	345	244
Right-of-use assets	285	329
License agreement	2,031	2,087
Goodwill	1,034	1,034
Total assets	<u>\$ 16,647</u>	<u>\$ 21,078</u>
Liabilities and stockholders' equity:		

Accounts payable and accrued liabilities	\$ 1,348	\$ 2,666
Current portion of long-term obligations	196	203
Long-term obligations	118	159
Stockholders' equity	14,985	18,050
Total liabilities and stockholders' equity	<u>\$ 16,647</u>	<u>\$ 21,078</u>

View original content to download multimedia <http://www.prnewswire.com/news-releases/achieve-reports-financial-results-for-first-quarter-2020-and-provides-update-on-cytisinicline-development-program-301058990.html>

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