May 9, 2024

Achieve Life Sciences Reports Financial Results for First Quarter 2024 and Provides Corporate Update

Company to host conference call at 4:30 PM EDT today, Thursday, May 9, 2024

SEATTLE and VANCOUVER, British Columbia, May 09, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced its financial results for the first quarter of 2024 and provided an update on the cytisinicline development program.

Recent Highlights

- Published Phase 2 ORCA-V1 clinical trial results in the *Journal of the American Medical Association Internal Medicine (JAMA IM)*
- Advanced plans for the initiation of the long-term cytisinicline exposure trial (ORCA-OL)
- Presented data from Phase 3 ORCA-2 and ORCA-3 trials, and Phase 2 ORCA-V1 trial at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting
- Announced an equity financing totaling up to $124.2 million that included initial upfront gross proceeds of $60.0 million and up to an additional approximately $64.2 million of gross proceeds upon exercise of milestone-driven warrants

“It has been a busy and exciting first quarter of 2024. Our focus has been to ensure adequate resources and execution of activities required for the cytisinicline NDA submission in the United States. We are pleased with the progress we’ve made on preparations for the ORCA-OL trial, which we expect to initiate in the coming weeks,” stated John Bencich, Chief Executive Officer of Achieve. “We are also pleased to once again this quarter have our trial results presented and published in highly esteemed medical forums, demonstrating the quality and standard of excellence of our clinical development program.”

ORCA-V1 Results Published in *JAMA Internal Medicine*
The positive Phase 2 ORCA-V1 trial results for cytisinicline as a treatment for vaping cessation were published in *JAMA IM.* Cytisinicline treatment more than doubled the odds of achieving abstinence and was well tolerated. Achieve expects to conduct an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in 2024 to discuss future plans for an expanded label in e-cigarette cessation.

ORCA-OL on Target to Initiate Enrollment in May 2024
Achieve and the FDA reached agreement that a single, open-label study evaluating for long-term safety exposure of cytisinicline will be sufficient to enable a New Drug Application (NDA) submission, now anticipated in the first half of 2025. The open-label trial, ORCA-OL, is on target to initiate in May 2024 and will recruit from the over 1,700 participants from earlier trials to efficiently generate longer-term safety data of cytisinicline treatment for up to one year.

Clinical Data Presented at Annual Society for Research on Nicotine and Tobacco Conference
Achieve presented three cytisinicline clinical data abstracts during the Annual SRNT conference. These included Phase 3 trials ORCA-2 and ORCA-3, and the Phase 2 trial ORCA-V1. In addition to the trial results, for the first time, survey results from Phase 3 participants revealed that 69% of those who received cytisinicline experienced success in quitting smoking and 22% experienced a significant reduction in smoking. Participants attributed their success to cytisinicline, citing reduced cravings and manageable side effects. Almost all participants expressed willingness to recommend cytisinicline to others. ORCA-3 confirmed higher quit rates with cytisinicline compared to placebo, without an increased relapse risk. Additionally, ORCA-V1 demonstrated cytisinicline's potential for vaping cessation, with significantly increased quit rates and minimal side effects among e-cigarette users.

Registered Direct Offering and Concurrent Private Placement
In February 2024, Achieve entered into a securities purchase agreement with new and existing investors to raise up to approximately $124.2 million in gross proceeds that included initial upfront funding of $60.0 million and up to an additional approximately $64.2 million upon exercise of milestone-driven warrants. The proceeds support the ongoing clinical development of cytisinicline through NDA submission, including the ORCA-OL trial, to fund other cytisinicline-related research and clinical development activities and for working capital and general corporate purposes. Achieve expects proceeds from the registered direct offering and concurrent private placement, assuming the exercise of all of the milestone-driven warrants, plus existing cash, will be sufficient to fund its development of cytisinicline into 2026 and through potential FDA approval.

Financial Results
As of March 31, 2024, Achieve's cash, cash equivalents, and restricted cash totaled $66.4 million, reflecting the closing of the registered direct offering and concurrent private placement, which resulted in gross proceeds of $60.0 million prior to deducting placement agent fees and offering expenses. Total operating expenses for the first quarter ended March 31, 2024 were $6.0 million. The total net loss for the first quarter ended March 31, 2024 was $6.5 million. As of May 9, 2024, Achieve had 34,341,303 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EDT today, Thursday, May 9, 2024. To access the webcast, log on to the investor relations page of the Achieve website and use the

following link: 1Q24 Earnings Webcast. Alternatively, access to the live conference call is available by dialing (877) 269-7756 (U.S. & Canada) or (201) 689-7817 (International) and referencing conference ID 13744142. 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

Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. There are an estimated 28 million adults in the United States alone who smoke combustible cigarettes.[1] Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide and nearly half a million deaths in the United States annually.[2,3] More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.[3]

In addition, there are over 11 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.[4] Currently, there are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for the treatment of nicotine addiction and has not been approved by the Food and Drug Administration for any indication in the United States. For more information on cytisinicline and Achieve visit www.achievelifesciences.com.

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 timing and nature of cytisinicline clinical development and regulatory review and approval, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability 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 of macroeconomic and geopolitical environment,

including inflation, increased volatility in interest rates and the debt and equity markets, instability in the global banking system, global health crises and pandemics and geopolitical conflict 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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References

[1]Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

[2]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

[3]U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

[4]Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182.

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

	Three months ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	2,799	5,534
General and administrative	3,183	3,044
Total operating expenses	5,982	8,578
Loss from operations	(5,982)	(8,578)
Other income (expense)	(512)	(414)
Net loss	$ (6,494)	$ (8,992)
Basic and diluted net loss per share	$ (0.26)	$ (0.50)

Weighted average number of basic and diluted common shares	25,048,134	17,917,769

Consolidated Balance Sheets
(In thousands)

	March 31, 2024	December 31, 2023
Assets:		
Cash and cash equivalents	$ 66,398	$ 15,546
Prepaid expenses and other current assets	1,311	1,436
Other assets and restricted cash	94	92
Right-of-use assets	51	66
License agreement	1,141	1,197
Goodwill	1,034	1,034
Total assets	$ 70,029	$ 19,371
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,379	$ 4,088
Current portion of long-term obligations	53	63
Convertible debt	17,141	16,662
Long-term obligations	—	6
Stockholders' equity	49,456	(1,448)
Total liabilities and stockholders' equity	$ 70,029	$ 19,371

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Source: Achieve Life Sciences