March 28, 2024

Achieve Life Sciences Reports Financial Results for Fourth Quarter and Year-End 2023 and Provides Corporate Update

Company to host conference call at 4:30 PM EDT today, Thursday, March 28, 2024

SEATTLE and VANCOUVER, British Columbia, March 28, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced fourth quarter and year-end 2023 financial results and provided an update on the cytisinicline development program.

Recent Highlights

- Announced Company reached agreement with the U.S. Food and Drug Administration (FDA) on long-term cytisinicline exposure requirements to support a New Drug Application (NDA) submission
- Completed an equity financing of up to $124.2 million that included initial upfront gross proceeds of $60.0 million, prior to deducting placement agent fees and estimated offering expenses, and up to an additional approximately $64.2 million of gross proceeds upon exercise of milestone-driven warrants
- Presented data from Phase 3 ORCA-2 and ORCA-3 trials, and Phase 2 ORCA-V1 trial at Society for Research on Nicotine and Tobacco (SRNT)

John Bencich, Achieve's Chief Executive Officer, commented, "2023 marked a significant turning point for Achieve as we accomplished several key milestones, such as repeating successful efficacy and safety outcomes in the second Phase 3 ORCA-3 trial for smoking cessation, positive data from the Phase 2 ORCA-V1 trial for vaping, and significant progress in our discussions with the FDA to further our goal of bringing cytisinicline forward to aid the millions of individuals who are seeking treatment for nicotine dependence. We are appreciative of the strong support and confidence from our stakeholders, including new investors who participated in the recent financing and smoking cessation opinion leaders who share in our enthusiasm for cytisinicline's potential."

FDA Agreement on NDA Submission Requirement
Achieve and the FDA have reached agreement that a single, open-label study evaluating for long-term safety exposure of cytisinicline will be sufficient to complete the requirement and enable an NDA submission anticipated in the first half of 2025. Achieve plans to initiate the "ORCA-OL" open-label exposure trial in the second quarter of 2024, which will include investigators and sites who have participated in the ORCA clinical trial program (ORCA-2, ORCA-3, and ORCA-V1 studies).

Completed Registered Direct Offering and Concurrent Private Placement
The Company completed an equity financing of up to $124.2 million that included initial upfront gross proceeds of $60.0 million, prior to deducting placement agent fees and estimated offering expenses, and up to an additional approximately $64.2 million gross proceeds upon exercise of milestone-driven warrants. Achieve expects proceeds from the registered direct offering and concurrent private placement, assuming the exercise of all of the milestone-driven warrants, will be sufficient to fund its development of cytisinicline into 2026 and through potential FDA approval.

ORCA-2, ORCA-3 and ORCA-V1 Data Presented at Annual SRNT Conference
During the Annual Society for Research on Nicotine and Tobacco conference in March, the Company had three cytisinicline clinical data abstracts selected for podium presentation. The selected abstracts covered data from the Phase 3 ORCA-2 and ORCA-3 trials, alongside the Phase 2 ORCA-V1 trial, and presented compelling evidence on the potential efficacy and safety of cytisinicline for smoking and vaping cessation.

Results presented from the Phase 3 participant surveys, showed that 69% of survey respondents who received cytisinicline reported quitting smoking completely. For those on treatment that did not achieve full smoking abstinence, 22% reported a reduction of their smoking by over half. Nearly all participants who quit smoking attributed their success to cytisinicline and cited fewer cravings and tolerable side effects as the main reasons. Additionally, 97% reported they would recommend cytisinicline to others. The ORCA-3 trial further validated these survey results, demonstrating higher smoking abstinence rates with cytisinicline compared to placebo, without increased relapse risk after transitioning to placebo. Furthermore, the ORCA-V1 trial explored cytisinicline's potential in vaping cessation among 160 e-cigarette users, showing a significant increase in abstinence rates compared to placebo, with minimal side effects.

Financial Results
As of December 31, 2023, the Company's cash, cash equivalents, and restricted cash was $15.6 million. After giving effect to the February 2024 equity financing the Company's pro forma cash, cash equivalents, and restricted cash as of December 31, 2023, would have been $71.8 million. Total operating expenses for the fourth quarter and year ended December 31, 2023 were $4.4 million and $27.3 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2023 was $5.5 million and $29.8 million, respectively. As of March 28, 2024, Achieve had 34,251,911 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EDT Thursday, March 28, 2024. To access the webcast, log on to the investor relations page of the Achieve website and use the following link **4Q23 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 13744140. 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.[3] 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 anticipated proceeds from outstanding milestone-driven warrants, the sufficiency of Achieve's capital resources to fund the development of cytisinicline through potential FDA approval, the 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 on our business of macroeconomic conditions, including inflation, rising interest rates, instability in the global banking sector, and public health crises, such as the COVID-19 pandemic 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.

Investor Relations Contact
Nicole Jones
achv@cg.capital
(404) 736-3838

Media Contact
Glenn Silver
Glenn.Silver@Finnpartners.com
(646) 871-8485

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 December 31,		Twelve months ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	2,114	8,614	15,814	30,078
General and administrative	2,272	2,248	11,436	10,722
Total operating expenses	4,386	10,862	27,250	40,800
Loss from operations	(4,386)	(10,862)	(27,250)	(40,800)
Other income (expense)	(1,090)	(370)	(2,565)	(1,550)
Net loss	$ (5,476)	$ (11,232)	$ (29,815)	$ (42,350)
Basic and diluted net loss per share	$ (0.26)	$ (0.83)	$ (1.50)	$ (4.00)

Weighted average number of basic and diluted common shares	21,165,760	13,536,944	19,827,354	10,593,034

Consolidated Balance Sheets
(In thousands)

	December 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 15,546	$ 24,771
Prepaid expenses and other current assets	1,436	2,559
Other assets and restricted cash	92	66
Right-of-use assets	66	123
License agreement	1,197	1,418
Goodwill	1,034	1,034
Total assets	$ 19,371	$ 29,971
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 4,088	$ 5,470
Current portion of long-term obligations	63	58
Convertible debt	16,662	16,071
Long-term obligations	6	69
Stockholders' equity	(1,448)	8,303
Total liabilities and stockholders' equity	$ 19,371	$ 29,971

Source: Achieve Life Sciences