August 13, 2024

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

Company to host conference call at 4:30 PM EDT today, Tuesday, August 13, 2024

SEATTLE and VANCOUVER, British Columbia, Aug. 13, 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 second quarter of 2024 and provided an update on its cytisinicline development program.

Recent Highlights

- The FDA granted Breakthrough Therapy designation for cytisinicline treatment of nicotine e-cigarette, or vaping, cessation
- Completed refinancing and extended the maturity date of outstanding term loans with Silicon Valley Bank (SVB)
- Joined the U.S. Russell 3000® and Russell Microcap® Indexes
- Initiated ORCA-OL clinical trial evaluating long-term exposure of cytisinicline in people who smoke or use nicotine e-cigarettes
- Presented data from cytisinicline ORCA-V1 program at Society of General Internal Medicine (SGIM) Annual Meeting

“We are extremely proud of the significant milestones we have accomplished over the last few months, including the granting of Breakthrough Therapy designation for cytisinicline for vaping cessation, which highlights the urgent need for an effective treatment to help the millions of people who are battling nicotine vape addiction,” stated John Bencich, Chief Executive Officer of Achieve. “Additionally, we initiated and are making great progress in the ORCA-OL trial evaluating long-term cytisinicline exposure moving us closer to our expected NDA filing in the first half of 2025.”

Cytisinicline for Vaping Cessation Granted FDA Breakthrough Therapy Designation
The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. The designation aims to accelerate the development and review process for promising drugs that are intended to treat serious conditions and when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. There are currently no FDA-approved treatments specifically indicated for vaping cessation. Achieve plans to hold an End-of-Phase 2 meeting with the FDA's multidisciplinary team under this Breakthrough Therapy designation before the end of the year.

Refinanced Outstanding Loan with Silicon Valley Bank
Achieve announced that it has entered into a debt refinancing agreement of up to $20 million with SVB, a division of First-Citizens Bank & Trust Company (FCB). The new loan agreement refinances the existing debt facility with SVB and extends the maturity date from August 1, 2024 to December 1, 2027. Achieve's obligations under the prior agreement were satisfied in full, and the previous agreement was terminated in connection with the new contingent convertible debt agreement.

Joined Russell 3000® and Russell Microcap® Indexes
Achieve received its inclusion in the U.S. Russell 3000® and Russell Microcap® Indexes, which became effective July 1, 2024. This inclusion enhances the company's visibility among investors, reflecting Achieve's strong business fundamentals and market potential for cytisinicline as a treatment for nicotine dependence.

Initiated ORCA-OL Trial
The open-label, ORCA-OL trial, was initiated in May 2024 and will incorporate participants from earlier cytisinicline clinical trials to efficiently compile safety data over extended periods, specifically focused on subjects treated with cytisinicline for up to one year. Enrollment is ongoing at 29 clinical trial sites in the U.S. with more than half of the proposed 650 participants already enrolled on the study. The necessary clinical data from ORCA-OL is anticipated to be available to support an NDA submission in the first half of 2025.

ORCA-V1 Data Presented at the SGIM Annual Meeting
Data from the Phase 2 ORCA-V1 vaping cessation trial were presented at the SGIM Annual Meeting. The findings showed that cytisinicline more than doubled the likelihood of quitting nicotine e-cigarettes compared to placebo. Cytisinicline has shown promise in aiding smoking cessation and may also help individuals quit vaping.

Financial Results
As of June 30, 2024, the company's cash, cash equivalents, restricted cash and short-term investments total $61.3 million. Total operating expenses for the three and six months ended June 30, 2024 were $8.4 million and $14.4 million, respectively. The total net loss for the three and six months ended June 30, 2024 was $8.5 million and $15.0 million, respectively. As of August 13, 2024, Achieve had 34,341,303 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EDT today, Tuesday, August 13, 2024. To access the webcast, log on to the investor relations page of the Achieve website and use the following link: 2Q24 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 13747337. 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 approximately 29 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.[4] In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.[5] 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 on our business of, 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]VanFrank B, Malarcher A, Cornelius ME, Schecter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641.

[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]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.

[5]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 June 30,		Six months ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	5,113	4,585	7,912	10,119
General and administrative	3,318	3,129	6,501	6,173
Total operating expenses	8,431	7,714	14,413	16,292
Loss from operations	(8,431)	(7,714)	(14,413)	(16,292)
Other income (expense)	(30)	(525)	(542)	(939)
Net loss	$ (8,461)	$ (8,239)	$ (14,955)	$ (17,231)
Basic and diluted net loss per share	$ (0.25)	$ (0.43)	$ (0.50)	$ (0.93)

Weighted average number of basic and diluted common shares	34,318,709	19,048,627	29,683,422	18,486,322

Consolidated Balance Sheets
(In thousands)

	June 30, 2024	December 31, 2023
Assets:		
Cash, cash equivalents and short-term investments	$ 61,313	$ 15,546
Prepaid expenses and other current assets	1,206	1,436
Other assets and restricted cash	117	92
Right-of-use assets	35	66
License agreement	1,086	1,197
Goodwill	1,034	1,034
Total assets	$ 64,791	$ 19,371
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 4,861	$ 4,088
Current portion of long-term obligations	37	63
Current portion of convertible debt	8,804	16,662
Non-current portion of convertible debt	8,804	—
Long-term obligations	—	6
Stockholders' equity	42,285	(1,448)
Total liabilities and stockholders' equity	$ 64,791	$ 19,371

Source: Achieve Life Sciences