

August 11, 2022



Achieve Reports Financial Results for Second Quarter 2022 and Provides Corporate Update

Company to host conference call at 4:30 PM EDT today, August 11, 2022

SEATTLE and VANCOUVER, British Columbia, Aug. 11, 2022 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage clinical pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced second quarter 2022 financial results and provided an update on the cytisinicline clinical development program.

Recent Events & Highlights

- Reported statistically significant results from the Phase 3 ORCA-2 clinical trial of cytisinicline in 810 adult smokers
- Awarded \$2.5 million grant from the National Institutes of Health (NIH) to conduct ORCA-V1 Phase 2 trial of cytisinicline in nicotine e-cigarette users
- Initiated the Phase 2 ORCA-V1 clinical trial to evaluate cytisinicline in adult e-cigarette users

“We continue to build upon the progress of cytisinicline with the announcement of the initiation of the ORCA-V1 trial and the continued enrolment in ORCA-3, our final NDA-enabling smoking cessation clinical trial,” stated John Bencich, CEO of Achieve Life Sciences. “We remain focused on executing on our milestones and potentially expanding cytisinicline to e-cigarette and vaping users who currently have no FDA-approved cessation treatments.”

Reported Phase 3 ORCA-2 Results

In April, Achieve announced positive, statistically significant results in its Phase 3 ORCA-2 clinical trial of cytisinicline in 810 adult smokers across 17 clinical trial locations in the United States. ORCA-2 evaluated the efficacy and safety of 3mg of cytisinicline dosed 3 times daily for either 6 or 12-weeks compared to placebo in adult smokers. Both the primary and secondary endpoints demonstrated increased quit rates, showing 6-8 times increased odds of smoking abstinence when compared to placebo. Cytisinicline was well tolerated with single-digit rates of adverse events observed and no treatment-related serious adverse events reported.

Awarded \$2.5 Million from NIH for Phase 2 ORCA-V1 Trial

In June, Achieve was awarded \$2.5 million in grant funding from the NIH to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. In total, \$2.8 million has been awarded and is expected to cover approximately half of the ORCA-V1 trial costs.

Initiated Phase 2 ORCA-V1 Trial

Also in June, following the NIH grant award, Achieve initiated the ORCA-V1 clinical trial across five trial locations in the United States. Approximately 150 participants are planned to be randomized to receive 3mg of cytisinicline 3 times daily or placebo for 12 weeks in combination with standard behavioral support.

Financial Results

As of June 30, 2022, the company's cash, cash equivalents, and restricted cash were \$29.4 million. Total operating expenses for the three and six months ended June 30, 2022 were \$10.1 million and \$17.3 million, respectively. Total net loss for the three and six months ended June 30, 2022 was \$10.5 million and \$18.0 million, respectively.

As of August 11, 2022, Achieve had 9,681,855 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 PM EDT, Thursday, August 11, 2022. To access the webcast, please use the following link [2Q22 Earnings Webcast](#). Alternatively, you may access the live conference call by dialing (888) 645-4404 (Domestic) or (404) 267-0371 (International) and referencing conference ID 13731865. A webcast replay will be available approximately three 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. 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.^{1,2} 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.²

In addition, there are nearly 11 million adults in the United States who use e-cigarettes, also known as vaping.³ While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease.⁴ In 2021, e-cigarettes were the most commonly used tobacco product reported by 1.72 million high school students.⁵ Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped.⁶ 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 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, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, 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 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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References

¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

² U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

³ Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:1736–1742. DOI: 10.15585/mmwr.mm6946a4.

⁴ Ogunwale, Mumiye A et al. (2017) Aldehyde Detection in Electronic Cigarette Aerosols. ACS omega 2(3): 1207-1214. DOI: 10.1021/acsomega.6b00489].

⁵ Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors

Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(no. SS-5):1-29. DOI: 10.15585/mmwr.ss7105a1.

⁶Elizabeth C. Hair, Alexis A. Barton, Siobhan N. Perks, Jennifer Kreslake, Haijun Xiao, Lindsay Pitzer, Adam M. Leventhal, Donna M. Vallone, Association between e-cigarette use and future combustible cigarette use: Evidence from a prospective cohort of youth and young adults, 2017–2019, Addictive Behaviors, Volume 112, 2021, 106593, ISSN 0306-4603. DOI: 10.1016/j.addbeh.2020.106593.

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	7,207	9,227	11,595	14,869
General and administrative	2,866	2,075	5,704	4,417
Total operating expenses	<u>10,073</u>	<u>11,302</u>	<u>17,299</u>	<u>19,286</u>
Loss from operations	(10,073)	(11,302)	(17,299)	(19,286)
Other income (expense)	(395)	(9)	(742)	(24)
Net loss	<u>\$ (10,468)</u>	<u>\$ (11,311)</u>	<u>\$ (18,041)</u>	<u>\$ (19,310)</u>
Basic and diluted net loss per share	\$ (1.08)	\$ (1.53)	\$ (1.89)	\$ (2.85)
Weighted average number of basic and diluted common shares	9,647,726	7,390,600	9,553,757	6,764,688

Consolidated Balance Sheets
(In thousands)

	June 30, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	\$ 29,378	\$ 43,022
Prepaid expenses and other current assets	1,770	1,572

Other assets and restricted cash	240	183
Right-of-use assets	33	64
License agreement	1,530	1,641
Goodwill	1,034	1,034
Total assets	\$ 33,985	\$ 47,516
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 5,318	\$ 4,481
Current portion of long-term obligations	41	69
Convertible debt	15,460	14,920
Long-term obligations	—	4
Stockholders' equity	13,166	28,042
Total liabilities and stockholders' equity	\$ 33,985	\$ 47,516



Source: Achieve Life Sciences