August 7, 2025

Achieve Life Sciences Reports Second Quarter 2025 Financial Results; Provides Updates on Cytisinicline Program

Conference Call Scheduled for 8:30 AM EDT Today, August 7, 2025

SEATTLE and VANCOUVER, British Columbia, Aug. 07, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence for smoking cessation, today announced its financial results for second quarter 2025.

“This quarter represents a significant step forward for Achieve. After years of focused dedication, we’ve reached the major milestone of submitting our NDA for cytisinicline, established an innovative commercialization partnership with Omnicom, and secured financing to advance our vision,” said Rick Stewart, Chief Executive Officer of Achieve Life Sciences. “By combining our evidenced-based science with an agile, technology-driven commercialization strategy, cytisinicline, if approved, would be the first new pharmacotherapy option for nicotine dependence in nearly two decades.”

Second Quarter Highlights

- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults.
- Announced partnership with Omnicom to co-develop and execute a fully integrated launch strategy, leveraging the infrastructure and expertise of seven specialized agencies operating as a unified team with the goal of reducing commercial buildout costs, accelerating execution, and optimizing performance across all launch functions.
- Raised $49.3 million in gross proceeds from an underwritten public offering to support continued advancement of cytisinicline.
- Reached key requirements in the ORCA-OL long-term exposure trial including safety exposure data for ≥300 participants receiving at least six months of cumulative

cytisinicline treatment and at least 100 participants receiving one year of cumulative cytisinicline treatment.
- Announced publication of the Phase 3 ORCA-3 trial results in the *Journal of American Medical Association (JAMA) Internal Medicine* that evaluated cytisinicline for smoking cessation in 792 U.S. adults.

“Submitting the NDA on schedule is an important milestone that reflects the hard work and dedication of our team and partners,” said Dr. Cindy Jacobs, President and Chief Medical Officer of Achieve Life Sciences. “Cytisinicline is supported by a comprehensive clinical data package, and we’re committed to working closely with the FDA to advance this important potential treatment option for adults seeking to overcome nicotine dependence.”

Submitted Cytisinicline NDA to FDA for Smoking Cessation
In June 2025, Achieve met its target milestone with the submission of an NDA to the FDA for cytisinicline as a treatment for nicotine dependence in adults seeking to quit smoking. The submission marks a major milestone following a decade of research and is supported by positive results from the Phase 3 ORCA-2 and ORCA-3 trials, which showed significantly higher quit rates with cytisinicline compared to placebo, along with favorable long-term safety data from the ORCA-OL study. With nearly half a million smoking-related deaths annually in the U.S. and limited treatment options, cytisinicline has the potential to address a critical unmet public health need.

Announced Partnership with Omnicom to Execute Potential Cytisinicline U.S. Launch
To support a more cost-efficient, streamlined, and insight-driven path to launch, in June 2025, Achieve entered a strategic partnership with Omnicom to co-develop and execute a fully integrated, data-driven commercial launch strategy for cytisinicline. This collaboration brings together seven specialized Omnicom agencies operating as a single, unified team across brand development, medical and patient education, market access, public relations, media, and marketing technology. Together, Achieve and Omnicom are building a unified, AI-enabled launch platform that consolidates all core marketing functions, designed to enable the company to reduce the time, cost, and risk associated with constructing a traditional internal infrastructure. This partnership gives Achieve access to the scale, speed, and capabilities of a much larger organization, positioning the company to execute a high-impact launch that reflects both the magnitude of the opportunity and the urgency of addressing one of the most pressing public health challenges of our time.

Completed a $49.3 Million Public Offering of Securities
In June 2025, Achieve announced the closing of an underwritten public offering, consisting of 15 million shares of common stock and 16,766,666 accompanying warrants, raising gross proceeds of $45 million. Subsequently, in July 2025, the underwriters partially exercised their overallotment option to purchase an additional 1,419,896 shares for gross proceeds of $4.3 million. Achieve intends to use the proceeds to support the continued advancement of cytisinicline and for working capital and general corporate purposes. The company currently expects the funding will provide runway into the second half of 2026.

Completed the FDA Long-Term Exposure Requirements in ORCA-OL
Achieve has successfully met the FDA’s long-term safety requirements for cytisinicline, with over 300 participants completing at least six months of cumulative cytisinicline treatment and with at least 100 participants completing one year of cumulative treatment. The ORCA-OL clinical study enrolled 479 participants across 29 U.S. sites, providing key data to support the safety profile of cytisinicline in extended use. The six-month cumulative data were submitted as part of the NDA.

ORCA-3 Phase 3 Results Published in *JAMA Internal Medicine*
Results from the Phase 3 ORCA-3 trial have been published in *JAMA Internal Medicine*, reinforcing cytisinicline's potential as a smoking cessation treatment. The randomized, placebo-controlled study of 792 U.S. adult smokers confirmed its efficacy and tolerability at 6- and 12-week durations, with reduced cravings and increased quit rates through 24 weeks. Findings are consistent with the earlier ORCA-2 trial, supporting cytisinicline's targeted action on nicotine receptors.

Financial Results
As of June 30, 2025, the company's cash, cash equivalents, and marketable securities were $55.4 million. Total operating expenses for the three and six months ended June 30, 2025, were $12.6 million and $25.5 million, respectively. Total net loss for the three and six months ended June 30, 2025, was $12.7 million and $25.5 million, respectively.

Conference Call Details
Achieve will host a conference call at 8:30 am EDT today, Thursday, August 7, 2025. To access the webcast, please use the following link: 2Q25 Earnings Webcast. Alternatively, you may join the live conference call by dialing 877-269-7756 (U.S. & Canada) or 201-689-7817 (International) and referencing conference ID 13754433. A webcast replay will be available approximately three hours after the call and archived on the website for 90 days.

About Achieve Life Sciences, Inc.
Achieve Life Sciences is a late-stage specialty pharmaceutical company committed to addressing the global smoking health and nicotine dependence epidemic through the development and commercialization of cytisinicline. In June 2025, the company submitted its New Drug Application to the FDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its fully enrolled open-label safety study. Additionally, the company has completed a Phase 2 study with cytisinicline in vaping cessation and conducted a successful end-of-Phase 2 meeting with the FDA for a future vaping indication.

About Cytisinicline
There are approximately 29 million adults in the United States 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 approximately 17 million adults in the United States who use e-cigarettes, also known as vaping.[4] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[5] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. Cytisinicline has been granted Breakthrough Therapy designation by the FDA to address this critical need.

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 nicotine craving symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed as a

treatment of nicotine dependence for smoking cessation and has not been approved by the Food and Drug Administration for any indication in the United States.

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 expectations regarding the use of proceeds from the public offering, the timing and nature of cytisinicline clinical development and regulatory review and approval, data results and commercialization activities, the potential benefits of the partnership with Omnicom, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, and the successful commercialization of cytisinicline. All statements other than statements of historical fact are statements that could be deemed 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 and commercialization of cytisinicline; the risk that cytisinicline will not receive regulatory approval in a timely manner or at all, or be successfully commercialized; the risk that new developments in the smoking and vaping cessation landscapes 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 Achieve’s business of macroeconomic and geopolitical conditions, including fluctuating inflation, interest and tariff rates, volatility in the debt and equity markets, actual or perceived 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. 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 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 law.

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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] Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: https://dx.doi.org/ 10.15620/cdc/174583.

[5] Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924.

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

	Three months ended June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	6,707	5,113	13,804	7,912
General and administrative	5,856	3,318	11,653	6,501
Total operating expenses	12,563	8,431	25,457	14,413
Loss from operations	(12,563)	(8,431)	(25,457)	(14,413)
Other income (expense)	(155)	(30)	(88)	(542)
Net loss	$ (12,718)	$ (8,461)	$ (25,545)	$ (14,955)
Basic and diluted net loss per share	$ (0.37)	$ (0.25)	$ (0.74)	$ (0.50)
Weighted average number of basic and diluted common shares	34,685,072	34,318,709	34,685,072	29,683,422

Consolidated Balance Sheets
(In thousands)

	June 30, 2025	**December 31, 2024**
Assets:		
Cash, cash equivalents and marketable securities	$ 55,397	$ 34,360
Prepaid expenses and other current assets	1,506	2,107
Other assets and restricted cash	42	39
Right-of-use assets	93	119
License agreement	863	974
Goodwill	1,034	1,034

Total assets	$ 58,935	$ 38,633
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 5,970	$ 6,627
Current portion of long-term obligations	58	55
Current portion of convertible debt	1,208	—
Contingent consideration	1,337	1,149
Non-current portion of convertible debt	8,657	9,837
Other long-term obligations	37	66
Stockholders' equity	41,668	20,899
Total liabilities and stockholders' equity	$ 58,935	$ 38,633

Source: Achieve Life Sciences