March 24, 2026

# Achieve Life Sciences Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Updates

*Achieve also Announces Partnership with U.S.-based Adare Pharma Solutions for Cytisinicline Manufacturing*

*Conference Call Scheduled for 8:30 AM EDT Today, March 24, 2026*

SEATTLE and VANCOUVER, British Columbia, March 24, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Achieve) (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence, today announced financial results for the fourth quarter and full year 2025 and provided updates on the cytisinicline development program, including the announcement of its partnership with Adare Pharma Solutions (Adare).

“Achieve is fully committed to bringing cytisinicline to the millions of people who continue to struggle with nicotine dependence and need a new solution to help them quit. Much like GLP-1 therapies have transformed the way obesity is treated, shifting it from a lifestyle issue to a recognized medical condition, smoking cessation deserves the same evolution,” said Rick Stewart, President and Chief Executive Officer of Achieve. “Achieve is not quitting on smokers or people who want to quit vaping. We are relentlessly working towards the potential approval of cytisinicline, the initiation of the Phase 3 vaping trial, and a data-driven, highly targeted commercial launch approach.”

Achieve has selected Adare, based in the U.S., to manufacture cytisinicline drug product for potential commercial launch and beyond. Achieve expects this partnership will help decrease risks related to international importation of pharmaceuticals and reduce costs, including potential tariffs. Achieve has commenced the technology transfer to Adare.

In addition to potential cost-savings, the Adare partnership provides supply chain redundancy and U.S.-based contingency capacity. One manufacturer named in the cytisinicline NDA recently underwent an FDA current Good Manufacturing Practices inspection, where two observations related to solid oral dose manufacturing were identified,

which are being addressed through an ongoing communication with FDA of its remedial action plan. The company anticipates U.S. commercial launch in the first half of 2027.

Mr. Stewart commented further, “Establishing U.S. manufacturing with Adare increases our confidence in our supply chain and continues our strong progress towards launch.”

**Key Highlights**

- Made meaningful progress toward regulatory approval in smoking and vaping:
  - FDA accepted the cytisinicline NDA for treatment of nicotine dependence for smoking cessation in adults, assigning a PDUFA targeted action date of June 20, 2026.
  - Completed the ORCA-OL long-term exposure trial with 334 participants finishing the one-year study, providing comprehensive long-term safety data for cytisinicline and significantly exceeding the number of patients required for FDA review.
  - Cytisinicline was selected as one of the first nine therapies chosen for the inaugural FDA Commissioner’s National Priority Voucher for e-cigarette or vaping cessation. The voucher is designed to provide enhanced FDA communications and expedited review, once complete materials are submitted to the FDA.

- Preparation for commercial readiness in anticipation of launch:
  - Completed supply chain and market access readiness activities, including beginning implementation of third-party logistics provider and specialty pharmacy partner selection. Announced partnership with Omnicom across multiple, cross-functional agencies to create a data-driven commercial model designed to execute with precision, scale efficiently and accelerate meaningful engagement for patients and providers.

- Advanced scientific exchange surrounding nicotine dependence, including:
  - Complete results from its ORCA-3 trial were published in the *Journal of the American Medical Association (JAMA) Internal Medicine*. The authors concluded that ORCA-3 reaffirms cytisinicline’s efficacy and tolerability for smoking cessation in adult smokers at both 6- and 12-week treatment durations, including reduction in nicotine cravings and extended cessation benefits through 24 weeks.
  - Publication of new data in *Thorax* demonstrated that cytisinicline significantly increased continuous smoking abstinence versus placebo in both chronic obstructive pulmonary disease (COPD) and non-COPD subgroups. Despite more severe tobacco use histories and greater prior treatment exposure, participants with COPD achieved quit rates comparable to those without COPD.
  - Presented new data at the Society for Research on Nicotine and Tobacco (SRNT) 2026 Annual Meeting indicating that cytisinicline delivers meaningful quitting success, regardless of participants' prior use of smoking cessation medications or number of previous quit attempts.
  - Presented late-breaking survey data from ORCA-OL at SRNT, which followed participants for up to one year of treatment. The voluntary post-trial survey offered insights into patient-reported experiences with the extended use of cytisinicline beyond the 6- and 12-week courses previously studied.

“Our comprehensive clinical program demonstrates cytisinicline's potential to address a persistent, public health challenge,” said Mark Rubinstein, MD, Chief Medical Officer of Achieve. “The SRNT findings are particularly encouraging because they indicate that cytisinicline helps people quit smoking regardless of their prior treatment history or number of prior attempts, and, if approved, could offer hope to those who have struggled to quit. Combined with our published research on cytisinicline's tolerability profile, we have a comprehensive body of evidence that could represent a potential new standard of care in nicotine dependence treatment.”

**Financial Results**
As of December 31, 2025, the company’s cash, cash equivalents, and marketable securities were $36.4 million. Total operating expenses for the three and twelve months ended December 31, 2025, were $14.7 million and $54.9 million, respectively. Total net loss for the three and twelve months ended December 31, 2025, was $14.7 million and $54.7 million, respectively.

**Conference Call Details**
Achieve will host a conference call at 8:30 AM EDT today, Tuesday, March 24, 2026. To access the webcast, please use the following link: 4Q25 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 13758715. 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, Inc. is a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence. In September 2025, the company announced that its New Drug Application, submitted to the U.S. Food and Drug Administration (FDA) in June 2025, had been accepted for review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of June 20, 2026. The NDA is for cytisinicline to be used as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its 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 25 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 nearly 18 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[4] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. FDA has awarded the Commissioner’s National Priority Voucher for e-cigarette or vaping cessation and granted Breakthrough Therapy designation 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 FDA 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 Achieve makes regarding the timing, nature and outcome of cytisinicline clinical development and regulatory review and approval, data results, the timing, nature and success of Achieve's commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, the performance of Achieve's third-party manufacturing partners, and the successful launch and commercialization of cytisinicline. 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 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]National Center for Health Statistics. *National Health Interview Survey, 2023 and 2024*. 2026 (https://www.cdc.gov/nchs/nhis.htm).

[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]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 December 31, | | Twelve months ended December 31, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Operating expenses: | | | | |
| Research and development | 3,874 | 7,296 | 22,998 | 22,817 |
| General and administrative | 10,857 | 4,894 | 31,882 | 16,252 |
| Total operating expenses | 14,731 | 12,190 | 54,880 | 39,069 |
| Loss from operations | (14,731) | (12,190) | (54,880) | (39,069) |
| Other income (expense) | 69 | (170) | 232 | (758) |
| Net loss | $ (14,662) | $ (12,360) | $ (54,648) | $ (39,827) |
| Basic and diluted net loss per share | $ (0.28) | $ (0.36) | $ (1.25) | $ (1.24) |
| Weighted average number of basic and diluted common shares | 53,276,361 | 34,510,786 | 43,594,652 | 32,071,146 |

**Consolidated Balance Sheets**
**(In thousands)**

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| Assets: | | |
| Cash, cash equivalents and marketable securities | $ 36,404 | $ 34,360 |
| Prepaid expenses and other current assets | 3,485 | 2,107 |
| Other assets and restricted cash | 52 | 39 |
| Right-of-use assets | 64 | 119 |
| License agreement | 751 | 974 |
| Goodwill | 1,034 | 1,034 |
| Total assets | $ 41,790 | $ 38,633 |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued liabilities | $ 3,760 | $ 6,627 |

| | | |
|---|---|---|
| Current portion of long-term obligations | 61 | 55 |
| Current portion of convertible debt | 3,704 | — |
| Contingent consideration | 1,557 | 1,149 |
| Non-current portion of convertible debt | 11,185 | 9,837 |
| Other long-term obligations | 5 | 66 |
| Stockholders' equity | 21,518 | 20,899 |
| Total liabilities and stockholders' equity | $ 41,790 | $ 38,633 |


Source: Achieve Life Sciences