May 12, 2026

Achieve Life Sciences Reports First Quarter 2026 Financial Results and Provides Business Updates

Closed Private Placement of Up to $354 Million, Including $180 Million Upfront and $174 Million in Milestone-Driven Warrants

Appoints New CEO and Expands Board of Directors

Advances U.S.-based Manufacturing Transition & Partnership

Conference Call Scheduled for 8:30 AM EDT Today, May 12, 2026

SEATTLE and VANCOUVER, British Columbia, May 12, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Achieve or the Company) (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment for nicotine dependence, today announced financial results for the first quarter of 2026 and provided corporate highlights, including the recent financing and leadership updates.

“Achieve is a mission-driven company. Nicotine dependence is one of the largest preventable public health hazards we know, and smoking remains the leading cause of preventable death,” said Andrew D. Goldberg, MD, Chief Executive Officer of Achieve. “If approved, cytisinicline would be the first new FDA-approved smoking cessation therapy in more than two decades, and could also be the first ever for vaping cessation. My job is to ensure we have the team, the capital, and the strategy to bring cytisinicline to patients.”

Dr. Goldberg continued, “This quarter reflects deliberate work to build the company for the launch ahead. We closed a transformational financing, strengthened our Board, and advanced our transition to U.S. manufacturing. The Company will provide additional commercial leadership updates today. We are building the foundation to execute fully, and that is what we intend to do.”

Key Highlights:

Capital Raise

- Closed a private placement of up to $354 million, including $180 million upfront and up to $174 million from milestone-based warrants that may be exercised at any time prior to, and up to 20 trading days following, FDA approval of cytisinicline. Backed by leading healthcare investors, the proceeds will be used to fund the ORCA-V2 Phase 3 trial for cytisinicline for e-cigarette cessation, the commercialization of cytisinicline, and for working capital and general corporate purposes.

Leadership Transition

- Appointed Andrew D. Goldberg, MD as Chief Executive Officer and a Board member. New directors Christopher Martin, Lucian Iancovici, MD, and Aaron E. Royston, MD, add expertise in commercialization, company building, and corporate governance. Tom King has decided to step down from the Board, with his last day of service on June 8, 2026. Dr. Iancovici will assume the role of Chairman of the Board. Jaime Xinos will also transition from the role of Chief Commercial Officer, effective May 31, 2026, after nearly 9 years of dedicated service to Achieve. The Company expresses its gratitude for her contributions to advancing cytisinicline through clinical development. In connection with this transition, the Company has reorganized its commercial leadership for the launch ahead, which will be detailed in a separate announcement today.

Manufacturing Partnership with Adare Pharma Solutions

- Announced Achieve partnered with U.S.-based Adare Pharma Solutions (Adare) to support its commercial manufacturing. Achieve also completed an analytical method technology transfer to the site, successfully manufactured its first cytisinicline engineering batch, and fully qualified all testing procedures at the facility.

Regulatory Milestone and Manufacturing Readiness

- Announced Achieve's prior third-party manufacturer facility received an Official Action Indicated classification by the U.S. Food and Drug Administration (FDA) related to general current Good Manufacturing Practice matters, with observations not specific to cytisinicline. As a result, Achieve expects to receive a Complete Response Letter from the FDA on or before June 20, 2026, the Prescription Drug User Fee Act goal date. The Company intends to resubmit its New Drug Application in the fourth quarter of 2026, naming Adare as its new and primary manufacturing partner for commercial supply. The Company's stated expectation is for U.S. commercial launch in the first half of 2027.

Scientific Data Advancement

- Published in *Nicotine & Tobacco Research*, which provided evidence that cytisinicline selectively interacts with the α4β2 nicotinic receptor while exhibiting minimal interaction with the 5-HT3 receptor, a key mechanism potentially underlying its gastrointestinal tolerability. These findings help explain the low nausea rates observed in clinical trials and support cytisinicline as a promising alternative for smoking cessation, particularly in individuals sensitive to medication-related side effects.
- Presented data at the Society for Research on Nicotine and Tobacco (SRNT) 2026 Annual Meeting from a pooled analysis of over 1,600 participants in the Phase 3 ORCA-2 and ORCA-3 trials. Cytisinicline for 12 weeks significantly increased

continuous abstinence versus placebo in patients with prior varenicline and bupropion use (32.4% vs. 6.0%; OR 7.5), supporting its potential for patients who have failed existing therapies.
- Presented late-breaking ORCA-OL post-trial survey data at SRNT, which followed participants for up to 52 weeks of cytisinicline treatment. Among survey respondents, 98% reported they would recommend cytisinicline to others, 88% reported fewer cravings compared to prior quit attempts, and 76% reported physical health improvement compared to before the study.

Financial Results
As of March 31, 2026, the Company's cash, cash equivalents, and marketable securities were $29.3 million, not including estimated net proceeds of approximately $168.6 million from the private placement, after deducting estimated agent fees and other expenses. Total operating expenses and net loss for the three months ended March 31, 2026 were $10.5 million and $10.2 million, respectively

Conference Call Details
Achieve will host a conference call at 8:30 AM EDT today, Tuesday, May 12, 2026. To access the webcast, please use the following link: 1Q26 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 13759781. 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]

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. The 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, the successful launch and commercialization of cytisinicline, the use of proceeds from the private placement of our securities in April 2026, and statements concerning Achieve Life Sciences' future plans and prospects. 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.

Achieve Contact
Nicole Jones
VP, Strategic Communications and Stakeholder Relations
ir@achievelifesciences.com
425-686-1510

References
[1]Agaku I. Tobacco Product Use among U.S. Adults, 2023–2024, NEJM, doi: 10.1056/EVIDpha2500339.

[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 March 31,	
	2026	2025
Operating expenses:		
Research and development	3,292	7,097
General and administrative	7,171	5,797
Total operating expenses	10,463	12,894
Loss from operations	(10,463)	(12,894)
Other income	295	67
Net loss	$ (10,168)	$ (12,827)
Basic and diluted net loss per share	$ (0.19)	$ (0.37)
Weighted average number of basic and diluted common shares	53,381,989	34,685,072

Consolidated Balance Sheets
(In thousands)

	March 31, 2026	December 31, 2025
Assets:		
Cash, cash equivalents and marketable securities	$ 29,269	$ 36,404
Prepaid expenses and other current assets	1,792	3,485
Other assets and restricted cash	265	52
Right-of-use assets	49	64
License agreement	696	751
Goodwill	1,034	1,034
Total assets	$ 33,105	$ 41,790
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 6,203	$ 3,760
Current portion of long-term obligations	51	61
Current portion of convertible debt	5,579	3,704
Contingent consideration	1,272	1,557
Non-current portion of convertible debt	9,322	11,185
Other long-term obligations	—	5
Stockholders' equity	10,678	21,518
Total liabilities and stockholders' equity	$ 33,105	$ 41,790

Source: Achieve Life Sciences