November 6, 2025

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

One of Only Nine Therapies Chosen for the Inaugural FDA Commissioner's National Priority Voucher for E-cigarette or Vaping Cessation

Conference Call Scheduled for 8:30 AM EST Today, November 6, 2025

SEATTLE and VANCOUVER, British Columbia, Nov. 06, 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, today announced its financial results for third quarter 2025 and confirmed its Prescription Drug User Fee Act (PDUFA) targeted action date of June 20, 2026, for cytisinicline for treatment of nicotine dependence for smoking cessation.

"The FDA's acceptance of our NDA for cytisinicline in smoking cessation is an important milestone for Achieve, reflecting the strength of our clinical development program," said Rick Stewart, Chief Executive Officer of Achieve Life Sciences. "The NDA acceptance recognizes years of scientific and operational commitment to addressing nicotine dependence as a serious medical condition, in an indication that has not seen a new therapy in nearly 20 years. Additionally, the FDA's recent award of the Commissioner's National Priority Voucher for vaping cessation highlights the potential for cytisinicline to become the first and only FDA-approved therapy for nicotine dependence for vaping cessation. The vaping cessation market represents a significant and growing unmet medical need, with approximately 60% of the 17 million adult e-cigarette users in the United States expressing a desire to quit."

Stewart continued, "The momentum behind cytisinicline, from regulatory milestones to our preparations for commercial readiness, underscores our commitment to delivering hope and better health outcomes for millions of people. The addition and expertise of Erik Atkisson as Chief Legal Officer further strengthens our leadership team as we prepare for this next phase. Our team is energized by the opportunity to pioneer a new standard of care for those seeking to quit smoking, and we remain deeply committed to improving the lives of people affected by nicotine dependence."

Recent Highlights

- Announced the U.S. Food and Drug Administration (FDA) accepted the cytisinicline New Drug Application (NDA) for treatment of nicotine dependence for smoking cessation in adults. The FDA assigned a PDUFA targeted action date of June 20, 2026.
- Awarded the FDA Commissioner's National Priority Voucher (CNPV) for cytisinicline for treatment of nicotine dependence for e-cigarette or vaping cessation.
- Announced new post hoc data were published in *Thorax* demonstrating that cytisinicline significantly improved smoking quit rates compared to placebo in adults with chronic obstructive pulmonary disease (COPD).
- Met key milestones in advancing cytisinicline NDA for smoking cessation, including submitting the 120-day safety update to the FDA, concluding the ORCA-OL long-term exposure trial and completing the fourth and final Data Safety Monitoring Committee (DSMC) review for cytisinicline.
- Appointed Erik Atkisson as Chief Legal Officer, bringing over 25 years of legal experience across clinical- and commercial-stage biopharmaceutical companies.

"We have delivered important advancements in our cytisinicline development program, including receiving our PDUFA targeted action date for our smoking cessation indication and the Commissioner's National Priority Voucher for vaping cessation," said Dr. Mark Rubinstein, Interim Chief Medical Officer of Achieve Life Sciences. "Additionally, new post hoc data published in *Thorax* showed consistent efficacy and safety results in adults with COPD, supporting further evaluation of the potential impact of cytisinicline in diverse populations. In parallel, completion of key ORCA-OL activities, including submission of the 120-day safety update for the NDA, the final participant visit, and the concluding DSMC review, marks meaningful progress as we advance our clinical and regulatory initiatives."

FDA Accepts Cytisinicline NDA for Treatment of Nicotine Dependence for Smoking Cessation

The FDA has accepted the cytisinicline NDA for treatment of nicotine dependence for smoking cessation in adults. The FDA has assigned a PDUFA targeted action date of June 20, 2026. The NDA is supported by data from more than 2,000 participants in the Phase 3 ORCA-2 and ORCA-3 trials, where cytisinicline demonstrated significantly higher smoking abstinence rates compared to placebo. The safety database includes over 400 participants with at least six months of cumulative cytisinicline exposure and more than 200 participants with at least one year of cumulative cytisinicline exposure.

FDA Awards Commissioner's National Priority Voucher for Cytisinicline for Vaping Cessation

Achieve was awarded a CNPV for cytisinicline as a treatment for nicotine dependence associated with e-cigarette or vaping cessation. Cytisinicline was one of only nine therapies to receive this inaugural designation, and the voucher is designed to provide enhanced FDA engagement and shorten review time to one to two months from the standard 10–12 months once required materials are submitted. Cytisinicline, which has demonstrated clinical efficacy in the Phase 2 ORCA-V1 trial and holds Breakthrough Therapy designation, is being advanced as a potential first-in-class treatment for vaping cessation for a growing public health need affecting millions of Americans.

Published New Post Hoc Data in *Thorax*
The new data in the *Thorax* publication showed that cytisinicline improved smoking quit rates in adults with COPD. This post hoc analysis, based on more than 1,600 participants from the Phase 3 ORCA-2 and ORCA-3 trials, demonstrated consistent efficacy and safety results across both subgroups, reinforcing cytisinicline as a potential treatment option for smoking cessation in high-risk populations.

Met Key Milestones in Advancing the Cytisinicline NDA for Smoking Cessation
Achieve met several key milestones in advancing the cytisinicline NDA for smoking cessation. The company submitted its comprehensive 120-day safety update to the FDA, including results from 411 participants with at least six months of cumulative exposure to cytisinicline and 214 with one year of cumulative exposure. Additionally, the ORCA-OL long-term safety trial has concluded, with all 334 participants completing one year of treatment, exceeding the FDA's requested thresholds for patient exposure prior to approval. In November, we announced completion of the fourth and final scheduled safety review by the DSMC for the ORCA-OL trial. Adverse events reviewed during the final DSMC meeting were mostly mild in severity, and no serious adverse events were deemed to be treatment related. The DSMC found no concerns with respect to drug safety.

Appointed New Chief Legal Officer
In October, Achieve announced the appointment of Erik Atkisson as Chief Legal Officer. Mr. Atkisson brings more than 25 years of legal experience across the pharmaceutical and biotechnology industries, with prior leadership roles at Rain Oncology, Eiger BioPharmaceuticals, Cytokinetics, Amneal Pharmaceuticals, and BioMarin. In his new role, he will oversee Achieve's legal strategy, corporate governance, compliance, and risk management. Mr. Atkisson's extensive legal, regulatory, and M&A background will be instrumental as the company advances cytisinicline through regulatory review and prepares for potential commercialization.

Financial Results
As of September 30, 2025, the company's cash, cash equivalents, and marketable securities were $48.1 million. Total operating expenses for the three and nine months ended September 30, 2025, were $14.7 million and $40.1 million, respectively. Total net loss for the three and nine months ended September 30, 2025, was $14.4 million and $40.0 million, respectively.

Conference Call Details
Achieve will host a conference call at 8:30 a.m. EST today, Thursday, November 6, 2025. To access the webcast, please use the following link: 3Q25 Earnings Webcast. Alternatively, you may join the live conference call by dialing 888-396-8049 (U.S. & Canada) or 416-764-8646 (International) and referencing conference ID 13756406. 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 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. 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 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 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. 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 September 30,		Nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	5,320	7,609	19,124	15,521
General and administrative	9,372	4,857	21,025	11,358
Total operating expenses	14,692	12,466	40,149	26,879
Loss from operations	(14,692)	(12,466)	(40,149)	(26,879)
Other income (expense)	251	(46)	163	(588)
Net loss	$ (14,441)	$ (12,512)	$ (39,986)	$ (27,467)
Basic and diluted net loss per share	$ (0.28)	$ (0.36)	$ (0.99)	$ (0.88)
Weighted average number of basic and diluted common shares	51,017,662	34,355,050	40,189,095	31,251,997

Consolidated Balance Sheets
(In thousands)

	September 30, 2025	December 31, 2024

Assets:		
Cash, cash equivalents and marketable securities	$ 48,114	$ 34,360
Prepaid expenses and other current assets	1,941	2,107
Other assets and restricted cash	65	39
Right-of-use assets	79	119
License agreement	807	974
Goodwill	1,034	1,034
Total assets	$ 52,040	$ 38,633
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 7,024	$ 6,627
Current portion of long-term obligations	59	55
Current portion of convertible debt	1,204	—
Contingent consideration	1,443	1,149
Non-current portion of convertible debt	8,674	9,837
Other long-term obligations	21	66
Stockholders' equity	33,615	20,899
Total liabilities and stockholders' equity	$ 52,040	$ 38,633

Source: Achieve Life Sciences