UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): March 11, 2025

ACHIEVE LIFE SCIENCES, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**033-80623**	**95-4343413**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
22722 29th Drive SE, Suite 100 Bothell, WA		**98021**
1040 West Georgia, Suite 1030 Vancouver, BC, Canada		**V6E 4H1**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (604) 210-2217

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, par value $0.001 per share	ACHV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 11, 2025, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Achieve Life Sciences, Inc. dated March 11, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The information in Item 2.02 of this Form 8-K and Exhibit 99.1 attached hereto is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHIEVE LIFE SCIENCES, INC.

Date: March 11, 2025

/s/ MARK OKI

Mark Oki
Chief Financial Officer (Principal Financial Officer)

Exhibit 99.1

Achieve Life Sciences Reports Financial Results for Fourth Quarter and Year-End 2024 and Provides Update on the Cytisinicline Development Program

Reiterates Planned Cytisinicline NDA Submission Expected at the End of Q2 2025

Company to Host Conference Call at 8:30 AM EDT Today, Tuesday, March 11, 2025

SEATTLE and VANCOUVER, British Columbia, March 11, 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 the fourth quarter and year-end 2024 and reiterated its plans to submit its New Drug Application (NDA) for cytisinicline at the end of the second quarter of 2025.

Recent Highlights

- Reached key milestones in the ORCA-OL long-term exposure trial, including completion of enrollment and meeting the requirement of 300 participants receiving six months of cumulative cytisinicline treatment, as required for the submission of the new drug application (NDA)
- Announced positive outcomes from two data safety monitoring committee (DSMC) reviews with no safety concerns in the ORCA-OL clinical trial
- Appointed Dr. Kristen Slaoui and Nancy Phelan to the Board of Directors, bringing extensive leadership experience in corporate strategy and commercialization
- Appointed Mark Oki as Chief Financial Officer to oversee the company's financial strategy and operational initiatives
- Announced the successful outcome of the End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for defining cytisinicline development as a treatment for vaping cessation

"We are thrilled with our progress to date and excited to have the NDA submission on track for the end of next quarter, furthering our mission to bring cytisinicline to market as the first new FDA-approved nicotine dependence treatment in nearly 20 years," said Rick Stewart, Achieve's Chief Executive Officer. "Over the last several months, we've reached key milestones enabling the NDA submission and deepened our leadership expertise to execute our strategy. We have a unique opportunity in the very near-term to make a significant impact on a critical public health crisis while driving long-term shareholder value."

Key Milestones Reached for ORCA-OL Clinical Trial
Achieve has successfully completed enrollment in the cytisinicline ORCA-OL clinical trial, which includes 479 participants across 29 U.S. sites. This study is evaluating the long-term safety of a 3 mg

cytisinicline regimen for smoking and vaping cessation, a key requirement for Achieve's NDA submission planned for the second quarter of 2025. Furthermore, the trial reached the goal of at least 300 participants completing six months of cumulative cytisinicline treatment, as required by the FDA for the company's planned NDA.

Announced Two Positive DSMC Reviews for ORCA-OL Clinical Trial
After two thorough reviews of the available safety data for the cytisinicline ORCA-OL long-term exposure clinical trial, the DSMC reported that no unexpected treatment-related adverse events were identified and that participant adherence to cytisinicline medication was excellent. The overall safety data remain consistent with prior findings. The DSMC concluded that the study may proceed as planned, without any modifications.

Appointed Two New Members Board of Directors
Achieve announced the appointment of Dr. Kristen Slaoui and Nancy Phelan to its Board of Directors, bringing extensive expertise in corporate strategy, commercialization, and healthcare innovation. Dr. Slaoui, Chief Corporate Development Officer at Galderma, has led major transactions and strategic initiatives, while Ms. Phelan, Senior VP at Trinity Life Sciences, specializes in data-driven digital transformation and customer engagement. Both directors will play key roles as Achieve progresses toward NDA submission and commercialization for cytisinicline.

Appointed New Chief Financial Officer
In December 2024, Mark Oki was appointed as Achieve's Chief Financial Officer and brings over 25 years of experience in financial leadership within the biotechnology and pharmaceutical industries. He oversees the company's financial strategy, including accounting, investor relations, and key administrative functions, to support Achieve's mission of advancing cytisinicline for the treatment of nicotine dependence. Mr. Oki's expertise will be crucial as Achieve moves towards NDA submission and commercialization.

Announced End-of-Phase 2 Meeting for Vaping Cessation
The End-of-Phase 2 meeting was held with the FDA to confirm alignment on the proposed Phase 3 study design. The FDA agreed that one well-controlled Phase 3 trial (ORCA-V2), in addition to the completed Phase 2 ORCA-V1 trial, would be acceptable for a vaping cessation indication as a supplemental NDA. Additionally, the company's safety exposure data from the ongoing ORCA-OL study was deemed sufficient for label expansion. In July 2024, the FDA granted Breakthrough Therapy designation for vaping cessation, aimed at accelerating development and review for treatments showing significant improvement over current therapies. Dependent on availability of funding, Achieve plans to initiate the Phase 3 ORCA-V2 trial in the first half of 2026.

Financial Results
As of December 31, 2024, the company's cash, cash equivalents, and marketable securities was $34.4 million. Total operating expenses for the quarter and year ended December 31, 2024 were $12.2 million and $39.1 million, respectively. Total net loss for the quarter and year ended December 31, 2024 was $12.4 million and $39.8 million, respectively. As of March 11, 2025, Achieve had 34,685,072 shares outstanding.

Conference Call Details
Achieve will host a conference call at 8:30 am EDT today, Tuesday, March 11, 2025. To access the webcast, please use the following link: 4Q24 Earnings Webcast. Alternatively, you may access the live conference call by dialing 877-269-7756 (U.S. & Canada) or 1 201-689-7817 (International), referencing conference ID 13751745. 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. The company has successfully completed two Phase 3 studies with cytisinicline for smoking cessation and one Phase 2 study with cytisinicline in vaping cessation. The company has fully enrolled its ongoing open-label safety study with cytisinicline and plans to submit its new drug application for smoking cessation in Q2 2025. Achieve has also conducted a successful end-of-Phase 2 meeting with the FDA for a future vaping indication.

About Cytisinicline
There are approximately 29 million adults 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 over 11 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 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 for the treatment of nicotine addiction 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 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, 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 our 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, 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.

Investor Relations Contact
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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]Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

[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 December 31,		Twelve months ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	7,296	2,114	22,817	15,814
General and administrative	4,894	2,272	16,252	11,436
Total operating expenses	12,190	4,386	39,069	27,250
Loss from operations	(12,190)	(4,386)	(39,069)	(27,250)
Other income (expense)	(170)	(1,090)	(758)	(2,565)
Net loss	$ (12,360)	$ (5,476)	$ (39,827)	$ (29,815)
Basic and diluted net loss per share	$ (0.36)	$ (0.26)	$ (1.24)	$ (1.50)
Weighted average number of basic and diluted common shares	34,510,786	21,165,760	32,071,146	19,827,354

Consolidated Balance Sheets
(In thousands)

	December 31, 2024	December 31, 2023
Assets:		
Cash, cash equivalents and short-term investments	$ 34,360	$ 15,546
Prepaid expenses and other current assets	2,107	1,436
Other assets and restricted cash	39	92
Right-of-use assets	119	66
License agreement	974	1,197
Goodwill	1,034	1,034
Total assets	$ 38,633	$ 19,371
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 6,627	$ 3,560
Current portion of long-term obligations	55	63
Current portion of convertible debt	—	16,662
Non-current portion of convertible debt	9,837	—
Contingent consideration	1,149	528
Other long-term obligations	66	6
Stockholders' equity	20,899	(1,448)
Total liabilities and stockholders' equity	$ 38,633	$ 19,371