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): November 7, 2024

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 November 7, 2024, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 7, 2024
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: November 7, 2024

/s/ Richard Stewart

Richard Stewart
Chief Executive Officer (Principal Executive and Financial Officer)

Exhibit 99.1

Achieve Life Sciences Reports Financial Results for Third Quarter 2024 and Provides Corporate Update

Company to host conference call at 4:30 PM EST today,
Thursday, November 7, 2024

SEATTLE, Wash and VANCOUVER, British Columbia, November 7, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for the treatment of nicotine dependence, today announced its financial results for the third quarter of 2024 and provided an update on its cytisinicline development program.

Recent Highlights

- Completed enrollment in the Phase 3 ORCA-OL clinical trial and announced first Data Safety Monitoring Committee Meeting successfully conducted
- Presented at the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) Joint Public Meeting on smoking cessation priorities
- Granted Breakthrough Therapy designation by the FDA for cytisinicline treatment of nicotine e-cigarette, or vaping, cessation
- Announced changes in the Executive Leadership team and Board of Directors with the appointment of Richard Stewart as Chief Executive Officer and Thomas King as Executive Chairman of the Board of Directors
- Initiated the formation of a dedicated U.S. product launch preparedness team, highlighted by the promotion of Jaime Xinos to Chief Commercial Officer and the addition of Dr. Mark Rubinstein, a leading expert in nicotine dependence, as the new Head of Medical Affairs

“This is an incredibly exciting time at Achieve, as we remain steadfastly focused on advancing cytisinicline to address the urgent need for effective smoking and vaping cessation solutions,” stated Rick Stewart, Chief Executive Officer of Achieve. "With increased attention at the regulatory level and in the media on nicotine dependence, coupled with the lack of innovation in this field for over 20 years, we are committed to bringing the first new prescription therapy to market. We remain on track for our planned NDA submission in the second quarter of 2025 and are driven by the potential to make a meaningful difference in public health.”

Completed Enrollment for ORCA-OL Trial
Achieve has successfully completed enrollment in the 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. The trial rapidly enrolled in just over four months and

Achieve believes the number of participants will be sufficient to meet the long-term safety requirements for submission. Additionally, the trial's Data Safety Monitoring Committee completed its initial review and concluded that there are no safety concerns, the overall safety profile appears to be excellent, and the study may proceed as planned with no modifications.

Presented at the FDA and NIH Joint Public Meeting
Dr. Cindy Jacobs, President and Chief Medical Officer, represented Achieve at the FDA and NIH Joint Meeting, where she emphasized the urgent need for increased industry and agency collaboration to advance treatment options for smoking cessation and nicotine dependence. Dr. Jacobs highlighted that cytisinicline is currently the only late-stage treatment in clinical development that has successfully demonstrated cessation efficacy and excellent tolerability in two randomized Phase 3 trials conducted in over 1,600 participants. Full comments from the public meeting have been submitted to the public docket and are available on the FDA website.

Granted Breakthrough Therapy Designation for Cytisinicline Vaping Cessation Indication
In July, the FDA granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation, which is intended to expedite the development and review of treatments for serious conditions that show promising clinical evidence of significant improvement over current therapies.

Enhanced Leadership Team Expertise
Achieve's recent leadership appointments underscore a commitment to strategic growth and maximizing shareholder value. With Richard Stewart returning as CEO and Thomas King serving as Executive Chairman, Achieve is well-positioned to drive its focused growth strategy forward. The commercial launch readiness team will be led by Chief Commercial Officer, Jaime Xinos, who will focus efforts on execution of activities in preparation for cytisinicline entry to the U.S. market. Additionally, Dr. Mark Rubinstein's expertise in nicotine dependence, now as Head of Medical Affairs, will help to expand stakeholder awareness of Achieve and the potential public health impact of cytisinicline.

Financial Results
As of September 30, 2024, the company's cash, cash equivalents, restricted cash, and short-term investments totaled $42.9 million. Total operating expenses for the three and nine months ended September 30, 2024 were $12.5 million and $26.9 million, respectively. The total net loss for the three and nine months ended September 30, 2024 was $12.5 million and $27.5 million, respectively. As of November 7, 2024, Achieve had 34,389,946 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 pm EST today, Thursday, November 7, 2024. To access the webcast, please use the following link: 3Q24 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 13749877. A webcast replay will be available approximately three hours after the call and archived on the website for 90 days.

About Achieve and Cytisinicline

Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of 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 ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, 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 or be successfully commercialized; the risk that new developments in the smoking cessation landscape 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 inflation, volatile interest 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
Rich Cockrell
achv@cg.capital
(404) 736-3838

Media Contact
Glenn Silver
Glenn.Silver@Finnpartners.com
(646) 871-8485

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 September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	7,609	3,581	15,521	13,700
General and administrative	4,857	2,991	11,358	9,164
Total operating expenses	12,466	6,572	26,879	22,864
Loss from operations	(12,466)	(6,572)	(26,879)	(22,864)
Other income (expense)	(46)	(536)	(588)	(1,475)
Net loss	$ (12,512)	$ (7,108)	$ (27,467)	$ (24,339)
Basic and diluted net loss per share	$ (0.36)	$ (0.34)	$ (0.88)	$ (1.26)
Weighted average number of basic and diluted common shares	34,355,050	21,127,281	31,251,997	19,376,316

Consolidated Balance Sheets
(In thousands)

	September 30, 2024	December 31, 2023
Assets:		
Cash, cash equivalents and short-term investments	$ 42,911	$ 15,546
Prepaid expenses and other current assets	2,618	1,436
Other assets and restricted cash	304	92
Right-of-use assets	20	66
License agreement	1,030	1,197
Goodwill	1,034	1,034
Total assets	$ 47,917	$ 19,371
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 6,694	$ 4,088
Current portion of long-term obligations	22	63
Current portion of convertible debt	—	16,662
Non-current portion of convertible debt	9,823	—
Long-term obligations	—	6
Stockholders' equity	31,378	(1,448)
Total liabilities and stockholders' equity	$ 47,917	$ 19,371