
**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 9, 2023

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

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
Common Stock, par value \$0.001 per share	ACHV	The Nasdaq Capital 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 9, 2023, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the second quarter of 2023. 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 9, 2023
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 9, 2023

/s/ John Bencich

John Bencich

Chief Executive Officer (Principal Executive and Financial Officer)



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

Company to host conference call at 4:30 PM EST today, Thursday, November 9, 2023

SEATTLE, Wash and VANCOUVER, British Columbia, November 9, 2023 (GLOBE NEWSWIRE) — Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced third quarter 2023 financial results and provided an update on the cytisinicline development program.

Recent Business Highlights

- Announced publication of cytisinicline Phase 3 ORCA-2 smoking cessation trial in Journal of the American Medical Association (*JAMA*)
- Presented Phase 2 ORCA-V1 results at Society for Research on Nicotine and Tobacco Europe (SRNT-E)
- Participated in panel presentation at the American Society of Pharmacognosy (ASP) Annual Meeting
- Completed dosing of subjects in three ongoing NDA-supportive clinical studies

“This has been a pivotal year for Achieve and we made significant strides to continue our progress on advancing cytisinicline throughout the third quarter,” said John Bencich, CEO of Achieve. “Our primary focus remains on fulfilling FDA requirements to enable the submission of a New Drug Application for cytisinicline and engaging with partners who align with our vision for the substantial public health benefits of cytisinicline.”

ORCA-2 JAMA Publication

Results from the Phase 3 ORCA-2 trial were published in *JAMA* in July 2023. This trial, conducted in the United States, showcased the effectiveness and excellent tolerability of cytisinicline in adult smokers. Notably, cytisinicline exhibited significantly higher rates of biochemically verified smoking cessation when compared to a placebo, irrespective of whether the treatment lasted for 6 or 12 weeks. The rates of sustained abstinence remained statistically significant for up to 6 months and cytisinicline was well-tolerated. Additionally, the publication offered supplementary data indicating that individuals using cytisinicline experienced a swift and lasting reduction in cravings and the desire to smoke in contrast to those on the placebo during the initial 6 weeks of the treatment period.

ORCA-V1 SRNT-E Presentation

Phase 2 ORCA-V1 positive results were presented at the SRNT-E Annual Meeting. The presentation emphasized the primary endpoint analysis, revealing that 3 mg of cytisinicline administered three times daily for 12 weeks yielded a 2.6-fold ($p=0.035$) increase in the likelihood of vaping cessation



compared to a placebo among 160 daily nicotine vape users. Additional analyses presented indicated that vaping abstinence with cytisinicline treatment commenced during the second treatment week, with the odds of vaping cessation progressively improving throughout the 12-week treatment period. Similar to previous trials conducted in smoking cessation, cytisinicline treatment was well tolerated with only insomnia and abnormal dreams trending higher when compared to placebo, while rates of nausea and headache were lower for the 12-week cytisinicline treatment arm than observed in the placebo arm.

ASP Panel Presentation

Achieve management, John Bencich, Chief Executive Officer, and Richard Stewart, Executive Chairman of the Board of Directors, presented on a panel discussion “SEEDing Biomedical Innovation: Support for Small Businesses at National Institute of Health” at the 2023 American Society of Pharmacognosy (ASP) Annual Meeting. The panel highlighted the importance of industry and public partnerships in advancing new treatments, with Achieve representing an exemplary example.

Clinical Study Completion

Achieve has now completed recruitment and dosing of three NDA-supportive clinical studies evaluating QT interval prolongation, steady-state pharmacokinetics in smokers, and pharmacokinetics parameters in subjects with renal impairment. Data analysis and final study reports for all 3 studies are expected to be completed in early 2024.

Financial Results

As of September 30, 2023, the company’s cash, cash equivalents, and restricted cash was \$20.0 million. Total operating expenses for the three and nine months ended September 30, 2023 were \$6.6 million and \$22.9 million, respectively. Total net loss for the three and nine months ended September 30, 2023 was \$7.1 million and \$24.3 million, respectively. As of November 9, 2023, Achieve had 21,165,760 shares outstanding.



Conference Call Details

Achieve will host a conference call at 4:30 PM EDT Thursday, November 9, 2023. To access the webcast, log on to the investor relations page of the Achieve website and use the following link 3Q23 Earnings Webcast. Alternatively, access to the live conference call is available by dialing (877) 269-7756 (U.S. & Canada) or (201) 689-7817 (International) and referencing conference ID 13741438. A webcast replay will be available approximately two hours after the call and will be 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 an estimated 28 million adults in the United States alone 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.³ In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.⁴ Currently, there are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

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 withdrawal 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. For more information on cytisinicline and Achieve visit www.achievelifesciences.com.

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, 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, and the development and effectiveness of new treatments. 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 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 conditions, including inflation, rising interest rates, instability in the global banking sector, and public health crises, such as the COVID-19 pandemic 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.

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References

¹Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. *MMWR Morb Mortal Wkly Rep* 2023;72:475–483.

²World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

³U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

⁴Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:1173–1182.



Consolidated Statements of Loss
(In thousands, except per share and share data)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	3,581	9,869	13,700	21,464
General and administrative	2,991	2,770	9,164	8,474
Total operating expenses	<u>6,572</u>	<u>12,639</u>	<u>22,864</u>	<u>29,938</u>
Loss from operations	(6,572)	(12,639)	(22,864)	(29,938)
Other income (expense)	(536)	(438)	(1,475)	(1,180)
Net loss	<u>\$ (7,108)</u>	<u>\$ (13,077)</u>	<u>\$ (24,339)</u>	<u>\$ (31,118)</u>
Basic and diluted net loss per share	<u>\$ (0.34)</u>	<u>\$ (1.35)</u>	<u>\$ (1.26)</u>	<u>\$ (3.24)</u>
Weighted average number of basic and diluted common shares	<u>21,127,281</u>	<u>9,693,788</u>	<u>19,376,316</u>	<u>9,600,947</u>

Consolidated Balance Sheets
(In thousands)

	September 30, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	\$ 19,919	\$ 24,771
Prepaid expenses and other current assets	1,978	2,559
Other assets and restricted cash	74	123
Right-of-use assets	80	66
License agreement	1,252	1,418
Goodwill	1,034	1,034
Total assets	<u>\$ 24,337</u>	<u>\$ 29,971</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 4,021	\$ 5,470
Current portion of long-term obligations	61	58
Convertible debt	16,195	16,071
Long-term obligations	22	69
Stockholders' equity	4,038	8,303
Total liabilities and stockholders' equity	<u>\$ 24,337</u>	<u>\$ 29,971</u>