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 14, 2022

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.)**

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:

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

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 14, 2022, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2022. 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 14, 2022
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 14, 2022

/s/ John Bencich
John Bencich
Chief Executive Officer (Principal Executive and Financial Officer)

Exhibit 99.1

Achieve Reports Financial Results for Third Quarter 2022 and Provides Corporate Update

Company to host conference call at 4:30 PM EST today, November 14, 2022

SEATTLE, WA and VANCOUVER, British Columbia, November 14, 2022 (GLOBE NEWSWIRE) — Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage clinical pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced third quarter 2022 financial results and provided an update on the cytisinicline development program.

Highlights

- Completion of targeted enrollment in Phase 3 ORCA-3 clinical trial of cytisinicline in 750 adult smokers was announced in September
- Early completion of targeted enrollment in the Phase 2 ORCA-V1 clinical trial of cytisinicline in 150 adult nicotine e-cigarette users was announced in November
- New active pharmaceutical ingredient (API) suite construction completed by Sopharma, expanding the global commercial manufacturing capacity for cytisinicline

“Completing enrollment in the ORCA-3 trial this quarter and more recently, the ORCA-V1 trial, has moved us closer to potentially bringing a critical treatment option to people who wish to end their nicotine dependence,” stated John Bencich, CEO of Achieve Life Sciences. “We are excited to build upon the previously reported cessation benefit, safety, and tolerability of cytisinicline and look forward to releasing top-line data for both trials in the second quarter of next year.”

Completed Enrollment in Confirmatory Phase 3 ORCA-3 Trial

In September, Achieve announced the completion of targeted enrollment of 750 adult smokers in its confirmatory Phase 3 ORCA-3 clinical trial of cytisinicline being conducted across 20 clinical trial locations in the United States. The participants in ORCA-3 were randomized to one-of-three study arms to determine the efficacy and safety of cytisinicline administered for either 6 or 12 weeks, compared to placebo. Similar to the previously reported ORCA-2 trial, the primary endpoint is biochemically verified continuous abstinence during the last four weeks of treatment in the 6 and 12-week cytisinicline treatment arms compared to placebo. Each treatment arm will be compared independently to the placebo arm and the trial will be determined to be successful if either or both of the cytisinicline treatment arms show a statistical benefit compared to placebo. Topline ORCA-3 data are currently expected to be reported in Q2 of 2023.

Early Completion of Enrollment in Phase 2 ORCA-V1 Trial
In November, Achieve announced the early completion of targeted enrollment of 150 adult users of nicotine e-cigarettes in the Phase 2 ORCA-V1 clinical trial of cytisinicline being conducted across 5 clinical trial locations in the United States. Participants were randomized in this two-arm trial to receive either cytisinicline, dosed at 3 mg three times daily, or placebo, for a period of 12 weeks. All subjects are also receiving standardized behavioral support throughout the trial. The primary outcome assessment of ORCA-V1 will be continuous vaping abstinence during the final 4 weeks of treatment. ORCA-V1 is supported through grant funding from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH). Topline results are expected to be reported in Q2 of 2023.

Sopharma Expansion of Manufacturing Facility
Achieve's commercial manufacturing partner, Sopharma, financed and completed the build out of a new dedicated cytisinicline API purification suite at its primary manufacturing plant. At an estimated build out cost of more than €3 million, the newly completed API suite significantly expands the capacity to produce quantities of cytisinicline at a global scale. The new API suite complements Sopharma's capacity to produce nearly 3 billion tablets annually.

Financial Results
As of September 30, 2022, the company's cash, cash equivalents, and restricted cash were $18.2 million. Total operating expenses for the three and nine months ended September 30, 2022 were $12.6 million and $29.9 million, respectively. Total net loss for the three and nine months ended September 30, 2022 was $13.1 million and $31.1 million, respectively.

As of November 10, 2022, Achieve had 9,710,747 shares of common stock outstanding.

Conference Call Details
Achieve will host a conference call today at 4:30 PM EST, Monday, November 14, 2022. To access the webcast, please use the following link 3Q22 Earnings Webcast. Alternatively, you may access the live conference call by dialing (877) 269-7756 (Domestic) or (201) 689-7817 (International) and referencing conference ID 13733008. A webcast replay will be available approximately three 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. 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. [1,2] 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.[2]

In addition, there are nearly 11 million adults in the United States who use e-cigarettes, also known as vaping. [3] While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease.[4] In 2021, e-cigarettes were the most commonly used tobacco product reported by 1.72 million high school students.[5] Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped.[6] 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 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, 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 the COVID-19 pandemic or similar public health crises 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

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[2]U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.
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[4]Ogunwale, Mumiye A et al. (2017) Aldehyde Detection in Electronic Cigarette Aerosols. ACS omega 2(3): 1207-1214. DOI: 10.1021/acsomega.6b00489].
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ACHIEVE
LIFE SCIENCES

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	9,869	4,591	21,464	19,460
General and administrative	2,770	2,102	8,474	6,519
Total operating expenses	12,639	6,693	29,938	25,979
Loss from operations	(12,639)	(6,693)	(29,938)	(25,979)
Other income (expense)	(438)	2	(1,180)	(22)
Net loss	$ (13,077)	$ (6,691)	$ (31,118)	$ (26,001)
Basic and diluted net loss per share	$ (1.35)	$ (0.71)	$ (3.24)	$ (3.39)
Weighted average number of basic and diluted common shares	9,693,788	9,452,238	9,600,947	7,670,383

Consolidated Balance Sheets
(In thousands)

	September 30, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 18,197	$ 43,022
Prepaid expenses and other current assets	2,760	1,572
Other assets and restricted cash	239	183
Right-of-use assets	18	64
License agreement	1,475	1,641
Goodwill	1,034	1,034
Total assets	$ 23,723	$ 47,516
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 6,893	$ 4,481
Current portion of long-term obligations	23	69
Convertible debt	15,763	14,920
Long-term obligations	—	4
Stockholders' equity	1,044	28,042
Total liabilities and stockholders' equity	$ 23,723	$ 47,516