
**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): August 13, 2024

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:

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 August 13, 2024, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 13, 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: August 13, 2024

/s/ John Bencich

John Bencich

Chief Executive Officer (Principal Executive and Financial Officer)



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

Company to host conference call at 4:30 PM EDT today,
Tuesday, August 13, 2024

SEATTLE, Wash and VANCOUVER, British Columbia, August 13, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced its financial results for the second quarter of 2024 and provided an update on its cytisinicline development program.

Recent Highlights

- The FDA granted Breakthrough Therapy designation for cytisinicline treatment of nicotine e-cigarette, or vaping, cessation
- Completed refinancing and extended the maturity date of outstanding term loans with Silicon Valley Bank (SVB)
- Joined the U.S. Russell 3000[®] and Russell Microcap[®] Indexes
- Initiated ORCA-OL clinical trial evaluating long-term exposure of cytisinicline in people who smoke or use nicotine e-cigarettes
- Presented data from cytisinicline ORCA-V1 program at Society of General Internal Medicine (SGIM) Annual Meeting

"We are extremely proud of the significant milestones we have accomplished over the last few months, including the granting of Breakthrough Therapy designation for cytisinicline for vaping cessation, which highlights the urgent need for an effective treatment to help the millions of people who are battling nicotine vape addiction," stated John Bencich, Chief Executive Officer of Achieve. "Additionally, we initiated and are making great progress in the ORCA-OL trial evaluating long-term cytisinicline exposure moving us closer to our expected NDA filing in the first half of 2025."

Cytisinicline for Vaping Cessation Granted FDA Breakthrough Therapy Designation

The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. The designation aims to accelerate the development and review process for promising drugs that are intended to treat serious conditions and when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. There are currently no FDA-approved treatments specifically indicated for vaping cessation. Achieve plans to hold an End-of-Phase 2 meeting with the FDA's multidisciplinary team under this Breakthrough Therapy designation before the end of the year.

Refinanced Outstanding Loan with Silicon Valley Bank



Achieve announced that it has entered into a debt refinancing agreement of up to \$20 million with SVB, a division of First-Citizens Bank & Trust Company (FCB). The new loan agreement refinances the existing debt facility with SVB and extends the maturity date from August 1, 2024 to December 1, 2027. Achieve's obligations under the prior agreement were satisfied in full, and the previous agreement was terminated in connection with the new contingent convertible debt agreement.

Joined Russell 3000® and Russell Microcap® Indexes

Achieve received its inclusion in the U.S. Russell 3000® and Russell Microcap® Indexes, which became effective July 1, 2024. This inclusion enhances the company's visibility among investors, reflecting Achieve's strong business fundamentals and market potential for cytisinicline as a treatment for nicotine dependence.

Initiated ORCA-OL Trial

The open-label, ORCA-OL trial, was initiated in May 2024 and will incorporate participants from earlier cytisinicline clinical trials to efficiently compile safety data over extended periods, specifically focused on subjects treated with cytisinicline for up to one year. Enrollment is ongoing at 29 clinical trial sites in the U.S. with more than half of the proposed 650 participants already enrolled on the study. The necessary clinical data from ORCA-OL is anticipated to be available to support an NDA submission in the first half of 2025.

ORCA-V1 Data Presented at the SGIM Annual Meeting

Data from the Phase 2 ORCA-V1 vaping cessation trial were presented at the SGIM Annual Meeting. The findings showed that cytisinicline more than doubled the likelihood of quitting nicotine e-cigarettes compared to placebo. Cytisinicline has shown promise in aiding smoking cessation and may also help individuals quit vaping.

Financial Results

As of June 30, 2024, the company's cash, cash equivalents, restricted cash and short-term investments total \$61.3 million. Total operating expenses for the three and six months ended June 30, 2024 were \$8.4 million and \$14.4 million, respectively. The total net loss for the three and six months ended June 30, 2024 was \$8.5 million and \$15.0 million, respectively. As of August 13, 2024, Achieve had 34,341,303 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 PM EDT today, Tuesday, August 13, 2024. To access the webcast, log on to the investor relations page of the Achieve website and use the following link: [2Q24 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 13747337. 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 approximately 29 million adults in the United States alone who smoke combustible cigarettes.¹Tobacco 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 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.⁵ 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 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, 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, risks related to the impact of macroeconomic and geopolitical environment, including inflation, increased volatility in interest rates and the debt and equity markets, 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

¹VanFrank 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.

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.

⁴Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. *MMWR Morb Mortal Wkly Rep* 2023;72:475–483.

⁵Birdsey 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	5,113	4,585	7,912	10,119
General and administrative	3,318	3,129	6,501	6,173
Total operating expenses	<u>8,431</u>	<u>7,714</u>	<u>14,413</u>	<u>16,292</u>
Loss from operations	(8,431)	(7,714)	(14,413)	(16,292)
Other income (expense)	(30)	(525)	(542)	(939)
Net loss	<u>\$ (8,461)</u>	<u>\$ (8,239)</u>	<u>\$ (14,955)</u>	<u>\$ (17,231)</u>
Basic and diluted net loss per share	<u>\$ (0.25)</u>	<u>\$ (0.43)</u>	<u>\$ (0.50)</u>	<u>\$ (0.93)</u>
Weighted average number of basic and diluted common shares	<u>34,318,709</u>	<u>19,048,627</u>	<u>29,683,422</u>	<u>18,486,322</u>

Consolidated Balance Sheets
(In thousands)

	June 30, 2024	December 31, 2023
Assets:		
Cash, cash equivalents and short-term investments	\$ 61,313	\$ 15,546
Prepaid expenses and other current assets	1,206	1,436
Other assets and restricted cash	117	92
Right-of-use assets	35	66
License agreement	1,086	1,197
Goodwill	1,034	1,034
Total assets	<u>\$ 64,791</u>	<u>\$ 19,371</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 4,861	\$ 4,088
Current portion of long-term obligations	37	63
Current portion of convertible debt	8,804	16,662
Non-current portion of convertible debt	8,804	—
Long-term obligations	—	6
Stockholders' equity	42,285	(1,448)
Total liabilities and stockholders' equity	<u>\$ 64,791</u>	<u>\$ 19,371</u>