
**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): May 12, 2022

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.)

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

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 May 12, 2022, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 12, 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: May 12, 2022

/s/ John Bencich

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



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

Company to host conference call at 4:30 PM EDT today, May 12, 2022

SEATTLE, Wash and VANCOUVER, British Columbia, May 12, 2022— Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced first quarter 2022 financial results and provided an update on the cytisinicline clinical development program.

Recent Events & Highlights

- Reported clinically robust and statistically significant Phase 3 topline results from the ORCA-2 clinical trial of cytisinicline in adult smokers
- Following positive ORCA-2 results, Achieve updated its agreements with Silicon Valley Bank, providing access to an additional \$10.0 million of capital
- Cytisinicline development program overview presented at Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting
- Appointed Dr. Vaughn Himes to Achieve's Board of Directors

"Cytisinicline exceeded our expectations in the ORCA-2 trial by delivering impressive efficacy and tolerability in a difficult-to-treat population of smokers, who had lengthy and intense smoking histories, but who courageously attempted to quit smoking in the height of the COVID-19 pandemic," said John Bencich, Chief Executive Officer of Achieve. "We are delighted for those who were successful in ORCA-2 and inspired to continue our efforts to bring this important cytisinicline treatment to the FDA for review and potential approval as a new cessation option for the millions of people battling nicotine addiction."

Positive Phase 3 ORCA-2 Topline Results

The Phase 3 ORCA-2 trial of cytisinicline achieved statistically significant results in primary and secondary endpoints for both 6- and 12-week cytisinicline treatment compared to placebo, and was very well tolerated with single-digit rates of adverse events observed.

Subjects who received 12 weeks of cytisinicline treatment had 6.3 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p < 0.0001$). The abstinence rate during weeks 9-12 was 32.6% for cytisinicline compared to 7.0% for placebo.

Subjects who received 6 weeks of cytisinicline treatment had 8 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p < 0.0001$). The abstinence rate during weeks 3-6 was 25.3% for cytisinicline compared to 4.4% for placebo.



Updated Debt Facility Agreement with SVB

In connection with the positive ORCA-2 trial results, Achieve received approval from Silicon Valley Bank to access the remaining capital available under its \$25.0 million debt facility put in place in December 2021. Per the terms of the agreement, the remaining \$10.0 million of commitments are being made available to the Company through April 30, 2023. Amounts drawn under the remaining commitments will incur interest at the greater of 3.50% and the WSJ prime rate, and will be subject to interest only payments through April 30, 2024, and then amortize fully over the following 24 months. No amounts have been drawn to date and the Company will have the discretion to make draws under the facility through April 30, 2023.

Cytisinicline Development Program Presented at SRNT Annual Meeting

An overview of the cytisinicline development program was included in the “Promising New Smoking Cessation Pharmacotherapies” Symposium during the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting on March 16, 2022.

Dr. Vaughn Himes Appointed to the Board of Directors

In March, Achieve announced the appointment of Vaughn B. Himes, PhD, to Achieve’s Board of Directors. Dr. Himes currently serves as the Chief Technology Officer at Seagen, where he leads the manufacturing, supply chain, process sciences, and quality functions. He has more than 30 years of experience in product development and commercialization in the pharmaceutical and biotech industry, including previous roles as Senior Vice President of Technical Operations at ZymoGenetics, and Vice President of Worldwide Manufacturing Operations at Corixa Corporation.

Financial Results

As of March 31, 2022, the company’s cash, cash equivalents, and restricted cash was \$36.4 million. Total operating expenses for the three months ended March 31, 2022 was \$7.2 million. Total net loss for the three months ended March 31, 2022 was \$7.6 million. As of May 12, 2022, Achieve had 9,681,855 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 PM EDT, Thursday, May 12, 2022. To access the webcast, please use the following [link](#) [Q22 Earnings Webcast](#). Alternatively, you may access the live conference call by dialing (877) 472-9809 (U.S. & Canada) or (629) 228-0791 (International) and referencing conference ID 3887417. 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

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 Achieve’s focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.



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, the development and effectiveness of new treatments, and the intention to submit cytisinicline to the FDA for approval. 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 Russian military action in Ukraine; 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.

Investor Relations Contact

Rich Cockrell
achv@cg.capital
(404) 736-3838

Media Contact

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

References

¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

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.



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

	Three months ended March 31,	
	2022	2021
Operating expenses:		
Research and development	4,388	5,642
General and administrative	2,838	2,342
Total operating expenses	7,226	7,984
Loss from operations	(7,226)	(7,984)
Other income (expense)	(347)	(15)
Net loss	\$ (7,573)	\$ (7,999)
Basic and diluted net loss per share	\$ (0.80)	\$ (1.30)
Weighted average number of basic and diluted common shares	9,458,745	6,131,821

Consolidated Balance Sheets
(In thousands)

	March 31, 2022	December 31, 2021
	Assets:	
Cash and cash equivalents	\$ 36,337	\$ 43,022
Prepaid expenses and other current assets	1,355	1,572
Other assets and restricted cash	253	183
Right-of-use assets	49	64
License agreement	1,586	1,641
Goodwill	1,034	1,034
Total assets	\$ 40,614	\$ 47,516
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 3,951	\$ 4,481
Current portion of long-term obligations	59	69
Convertible debt	15,171	14,920
Long-term obligations	—	4
Stockholders' equity	21,433	28,042
Total liabilities and stockholders' equity	\$ 40,614	\$ 47,516