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 12, 2021

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, B.C., 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 August 12, 2021, Achieve Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended June 30, 2021. 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 12, 2021

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 12, 2021

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

Exhibit 99.1

Achieve Reports Financial Results for Second Quarter 2021 and Provides Corporate Update

SEATTLE, Wash and VANCOUVER, British Columbia, August 12, 2021-- 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 second quarter 2021 financial results and provided an update on the cytisinicline clinical development program.

Recent Events & Highlights

- Announced completion of enrollment in the Phase 3 ORCA-2 clinical trial evaluating the efficacy and safety of 3.0 mg cytisinicline dosed 3 times daily (TID) compared to placebo in adult smokers
- Awarded grant from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) for the evaluation of cytisinicline in cessation of nicotine e-cigarette use
- Issued two new patents from the United States Patent and Trademark Office covering the novel 3.0 mg TID cytisinicline dosing regimen
- Closed financing with gross proceeds of $23 million, prior to deducting underwriting discounts and offering expenses

“In the second quarter, we continued to demonstrate our commitment to stakeholders by delivering on key milestones that advance our clinical program, and ultimately, cytisinicline’s potential ability to help millions of people who struggle with nicotine addiction to live healthier lives,” commented John Bencich, Chief Executive Officer of Achieve. “We will remain committed to the execution of the combustible cigarette cessation program, while in parallel preparing for our anticipated expansion into the e-cigarette cessation indication in partnership with the NIH.”

Phase 3 ORCA-2 Trial Fully Enrolled

The Phase 3 ORCA-2 trial completed enrollment of 810 adult smokers at 17 clinical sites in the United States. The participants have been randomized to one of three study arms to determine the efficacy and safety of cytisinicline administered for either six or twelve weeks, compared to placebo. The primary endpoint is biochemically verified continuous abstinence during the last four weeks of treatment in the six and twelve-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-2 data results are expected to be reported within the first half of 2022.

Awarded Grant from NIH for Nicotine e-cigarette Cessation

Achieve announced that it has been awarded a grant from the NIH to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. The initial grant will be used to complete key clinical and regulatory activities enabling the next stage of the grant award and initiation of the Phase 2 ORCA-V1 clinical study evaluating cytisinicline in approximately 150 adult nicotine e-cigarette users in the United States.

Patents Issued for 3.0 mg TID Dosing Regimen

Achieve announced that the United States Patent and Trademark Office has issued U.S. Patent No. 11,083,715 and U.S. Patent No. 11,083,716 covering the novel 3.0 mg TID cytisinicline dosing regimen. Not including any patent term extensions to which Achieve may be entitled, the newly issued patents will expire in the third quarter of 2040. Upon approval of cytisinicline by the U.S. Food and Drug Administration (FDA), Achieve anticipates these patents would be included in the FDA's Orange Book, which lists approved drugs and related patent and exclusivity information.

Completed $23 Million Financing

In May 2021, Achieve announced the closing of an underwritten public offering of 3,285,714 shares of its common stock at a public offering price of $7.00 per share, which includes the exercise in full by the underwriters of their overallotment option to purchase additional shares of common stock. The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses, were $23.0 million.

Financial Results

As of June 30, 2021, the company's cash, cash equivalents, and restricted cash was $42.1 million. Total operating expenses for the three and six months ended June 30, 2021 were $11.3 million and $19.3 million, respectively. Total net loss for the three and six months ended June 30, 2021 was $11.3 million and $19.3 million, respectively.

As of August 12, 2021, Achieve had 9,452,223 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30pm Eastern time today, Thursday, August 12, 2021To access the webcast, log on to the investor relations page of the Achieve website at http://ir.achievelifesciences.com/events-and-webcasts. Alternatively, access to the live conference call is available by dialing (877) 472-9809 (U.S. & Canada) or (629) 228-0791 (International) and referencing conference ID 8694398. 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 and commercialization activities, the potential issuances of patents, the ability to provide patent protection for Achieve's cytisinicline program, the potential listing of the patents in the FDA's Orange Book, the potential market size for cytisinicline, the potential benefits 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

[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.

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	9,227	1,103	14,869	2,644
General and administrative	2,075	1,815	4,417	3,631
Total operating expenses	11,302	2,918	19,286	6,275
Loss from operations	(11,302)	(2,918)	(19,286)	(6,275)
Other income (expense)	(9)	(4)	(24)	33
Net loss	$ (11,311)	$ (2,922)	$ (19,310)	$ (6,242)
Basic and diluted net loss per share	$ (1.53)	$ (1.68)	$ (2.85)	$ (3.79)
Weighted average number of basic and diluted common shares	7,390,600	1,744,014	6,764,688	1,645,426

Consolidated Balance Sheets
(In thousands)

	June 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 42,001	$ 35,853
Prepaid expenses and other current assets	430	1,122
Property, equipment, other assets and restricted cash	254	279
Right-of-use assets	94	146
License agreement	1,752	1,864
Goodwill	1,034	1,034
Total assets	$ 45,565	$ 40,298
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 4,602	$ 2,843
Current portion of long-term obligations	68	92
Long-term obligations	41	77
Stockholders' equity	40,854	37,286
Total liabilities and stockholders' equity	$ 45,565	$ 40,298