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 14, 2023

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.)**
22722 29th Drive SE, Suite 100 Bothell, WA		**98021**
1040 West Georgia, Suite 1030 Vancouver, BC, Canada		**V6E 4H1**
(Address of Principal Executive Offices)		**(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 LL

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 14, 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 August 14, 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: August 14, 2023

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

Exhibit 99.1

Achieve Life Sciences Reports Financial Results for Second Quarter 2023 and Provides Corporate Update

Company to host conference call tomorrow, Tuesday, August 15, 2023, at 8:30 AM EDT

SEATTLE, Wash and VANCOUVER, British Columbia, August 14, 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 second quarter 2023 financial results and provided an update on the cytisinicline development program.

Recent Highlights

- Publication of Phase 3 ORCA-2 trial results in the *Journal of the American Medical Association* (*JAMA*)
- Reported statistically significant smoking cessation benefit for cytisinicline in the confirmatory Phase 3 ORCA-3 trial
- Announced Phase 2 ORCA-V1 trial results showing statistically significant vaping cessation benefit with cytisinicline treatment
- Closed equity financing with gross proceeds of approximately $16.5 million, prior to deducting placement agent commissions and estimated offering expenses
- Refinanced outstanding loan with Silicon Valley Bank (SVB)

"We've had a very exciting and eventful first half of 2023, with two additional clinical trials reading out with positive results for cytisinicline in both smoking and vaping cessation, and the recent publication of the completed Phase 3 ORCA-2 trial in the highly prestigious *Journal of the American Medical Association*," commented John Bencich, CEO of Achieve. "In the upcoming months, our primary emphasis remains on fulfilling essential prerequisites and completion of multiple documents that will enable the submission of a New Drug Application for cytisinicline in the first half of 2024. Concurrently, we are dedicated to advancing commercialization strategies and engaging in crucial discussions that hold the potential of making cytisinicline the first FDA-approved therapy for smoking cessation in nearly two decades."

***JAMA* Publication**

The positive Phase 3 ORCA-2 trial results for cytisinicline as a treatment for smoking cessation were published in *JAMA*. Authors concluded that both 6- and 12-week treatment durations of cytisinicline, with behavioral support, demonstrated “smoking cessation efficacy and excellent tolerability” in adult smokers. In addition to the previously reported cessation rates, the publication provided additional data demonstrating that cytisinicline participants had a rapid and sustained decline in cravings and smoking urges compared with placebo during the first 6 weeks of treatment.

Confirmatory Phase 3 ORCA-3 Trial Reported Positive Results

Achieve announced positive topline results from a second Phase 3 ORCA-3 trial, which confirmed the safety and efficacy of 3mg cytisinicline dosed three times daily versus placebo in 792 adult U.S. smokers. Consistent with the previously reported Phase 3 ORCA-2 study, ORCA-3 demonstrated a statistically significant benefit in helping smokers quit compared to placebo, with low rates of adverse events. Both the 6-week and 12-week treatment durations showed statistically significant smoking cessation rates during the last 4 weeks of treatment and continued smoking abstinence through the follow up period of 24 weeks.

Subjects had an average age of 53 years, smoked a median of 20 cigarettes per day at baseline, and had a median smoking history of 36 years with four prior quit attempts. Cytisinicline was well-tolerated, and no treatment-related serious adverse events were reported. The findings highlighted cytisinicline's potential as an effective and well-tolerated treatment option for those who suffer from nicotine dependence.

ORCA-V1 Positive Phase 2 Trial Results for Vaping Cessation

Statistically significant results from the Phase 2 ORCA-V1 trial were also reported in the second quarter of 2023. Participants who underwent 12 weeks of cytisinicline treatment showed a 2.6 times higher likelihood of quitting vaping during the last 4 weeks of treatment compared to the placebo group ($p=0.035$). The vaping cessation rate from weeks 9 to 12 was 31.8% for cytisinicline compared to 15.1% for placebo. Favorable results for cytisinicline were consistently observed in secondary endpoints, across various clinical trial sites, and among different demographics, including age, gender, race, and prior smoking history. Cytisinicline was well-tolerated, with no reports of serious adverse events.

Registered Direct Offering of $16.5 Million

Achieve completed a registered direct offering of shares of its common stock, pursuant to which the Achieve sold 3,000,000 shares at a price of $5.50 per share. The offering raised approximately $16.5 million in gross proceeds, prior to deduction placement agent fees and offering expenses. Current Achieve investors, including members of Achieve’s management, participated in the transaction.

Refinanced Outstanding Loan with Silicon Valley Bank

Achieve refinanced its previous debt agreement with SVB, a division of First-Citizens Bank. Achieve entered into a new contingent convertible debt agreement, which replaced the outstanding loan and accrued interest balance of $16.6 million from the previous debt agreement entered into on December 22, 2021. The new agreement extended the outstanding loan's maturity to December 22, 2024, providing a 12-month extension. Other provisions regarding interest rate, conversion rights and price, and repayment remained unchanged. 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.

Financial Results

As of June 30, 2023, the company's cash, cash equivalents, and restricted cash was $25.1 million. Total operating expenses for the three and six months ended June 30, 2023 were $7.7 million and $16.3 million, respectively. Total net loss for the three and six months ended June 30, 2023 was $8.2 million and $17.2 million, respectively. As of August 14, 2023, Achieve had 21,105,760 shares outstanding.

Conference Call Details

Achieve will host a conference call at 8:30 AM EDT Tuesday, August 15, 2023. To 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) 269-7756 (U.S. & Canada) or (201) 689-7817 (International) and referencing conference ID 13739274. 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 2022, approximately 2.5 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

[1]Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.
[2]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.
[3]U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.
[4]Park Lee E, Ren C, Cooper M, Cornelius M, Jamal A, Cullen KA. Tobacco Product Use Among Middle and High School Students – United States, 2022. Morbidity and Mortality Weekly Report, 2022; 71:45.

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	4,585	7,207	10,119	11,595
General and administrative	3,129	2,866	6,173	5,704
Total operating expenses	7,714	10,073	16,292	17,299
Loss from operations	(7,714)	(10,073)	(16,292)	(17,299)
Other income (expense)	(525)	(395)	(939)	(742)
Net loss	$ (8,239)	$ (10,468)	$ (17,231)	$ (18,041)
Basic and diluted net loss per share	$ (0.43)	$ (1.08)	$ (0.93)	$ (1.89)
Weighted average number of basic and diluted common shares	19,048,627	9,647,726	18,486,322	9,553,757

Consolidated Balance Sheets
(In thousands)

	June 30, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 25,071	$ 24,771
Prepaid expenses and other current assets	1,308	2,559
Other assets and restricted cash	99	123
Right-of-use assets	95	66
License agreement	1,308	1,418
Goodwill	1,034	1,034
Total assets	$ 28,915	$ 29,971
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,387	$ 5,470
Current portion of long-term obligations	60	58
Convertible debt	15,731	16,071
Long-term obligations	38	69
Stockholders' equity	9,699	8,303
Total liabilities and stockholders' equity	$ 28,915	$ 29,971