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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 12, 2020

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**ACHIEVE LIFE SCIENCES, INC.**  
(Exact name of Registrant as Specified in Its Charter)

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Delaware  
(State or Other Jurisdiction  
of Incorporation)

033-80623  
(Commission  
File Number)

95-4343413  
(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)

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 12, 2020, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Press release of Achieve Life Sciences, Inc. dated November 12, 2020</u></a>

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 12, 2020

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

## **Achieve Reports Financial Results for Third Quarter 2020 and Provides Corporate and Cytisinicline Development Update**

**SEATTLE, Wash and VANCOUVER, British Columbia, November 12, 2020**-- 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 third quarter 2020 financial results and provided an update on the cytisinicline clinical development program.

### **Recent Events & Highlights**

- Initiated the Phase 3 ORCA-2 clinical trial evaluating the efficacy and safety of 3 mg cytisinicline dosed 3 times daily compared to placebo in 750 adult smokers at 15 clinical sites in the United States
- Promoted John Bencich to Chief Executive Officer and Dr. Cindy Jacobs to President
- Presented successful results from the RAUORA, head-to-head non-inferiority clinical trial comparing cytisinicline and Chantix® (varenicline), at the Society for Research on Nicotine and Tobacco European (SRNT-E) Annual Meeting
- Presented mechanism of action data comparing 5-HT<sub>3</sub> receptor activity of cytisinicline vs. Chantix at SRNT-E, providing rationale for differentiated side effect profile of smoking cessation treatments
- Announced smoking cessation Key Opinion Leader Virtual Roundtable to be held on November 17, 2020

“With the initiation of the Phase 3 ORCA-2 trial and the breakthrough evidence, both mechanistically and clinically, in support of cytisinicline in comparison to Chantix, the third quarter of 2020 has undeniably been the most pivotal in the history of our company,” commented John Bencich, Chief Executive Officer of Achieve. “Our primary focus in the coming months will be enrollment and execution of ORCA-2, while continuing to explore opportunities for commercialization and expansion into new therapeutic indications, digital health technologies, and audiences who may benefit from cytisinicline, specifically, users of vapes or e-cigarettes.”

### **Phase 3 ORCA-2 Trial Initiation**

Achieve’s first Phase 3 ORCA-2 trial was initiated in October 2020 and will randomize 750 U.S. smokers to one of three study arms to determine the efficacy and safety of cytisinicline administered for either 6 or 12 weeks, compared to placebo. The primary endpoint is biochemically verified continuous abstinence during the last 4 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.

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### **Management Team Update**

In September, the Company announced the promotion of John Bencich to Chief Executive Officer and Dr. Cindy Jacobs to President. Mr. Bencich has been serving as Achieve's Chief Financial and Operating Officer since 2017 and will join the Board of Directors in his role. Dr. Jacobs has been serving as the Chief Medical Officer of Achieve since 2017 and will continue in her role leading the regulatory and clinical development efforts for cytisinicline. Rick Stewart will remain with Achieve as the Executive Chairman of the Board of Directors and Dr. Anthony Clark will remain in his role as Chief Scientific Officer.

### **RAUORA: Significantly Fewer Adverse Events and Higher Quits Rates for Cytisinicline vs Chantix**

Final results from the New Zealand RAUORA Phase 3 non-inferiority clinical trial comparing cytisinicline to varenicline (Chantix) in Māori (indigenous New Zealanders) and whānau (family) of Māori were presented at the SRNT-E Annual Meeting in September 2020. Results showed that cytisinicline met the pre-specified non-inferiority endpoint and was trending towards superiority demonstrating a 4.29% improvement in quit rates in favor of cytisinicline. Subjects in the cytisinicline arm were approximately one and a half times more likely to have quit smoking at 6 months compared to subjects who received varenicline. Importantly, significantly fewer overall adverse events (AEs) were reported in cytisinicline-treated subjects. Of the subjects who experienced AEs (111 in the cytisinicline arm compared to 138 in the varenicline arm), there was significantly less nausea and vivid dreams.

### **MOA Data Explaining Reduced Nausea and Vomiting with Cytisinicline Presented at SRNT-E**

Data presented at the SRNT-E Annual Meeting in September 2020 provides a rationale based on detailed receptor pharmacology to explain why the incidence of nausea and vomiting associated with cytisinicline appears to be consistently lower than that seen with Chantix. The preclinical study, conducted at the University of Cambridge Department of Biochemistry, was designed to examine the in vitro binding characteristics of cytisinicline compared to varenicline at the human 5-HT3 receptor. The study reported an IC50 of 0.50 mM for cytisinicline and 0.25  $\mu$ M for varenicline, representing a 2000-greater fold agonist binding affinity to the 5-HT3 receptor for varenicline compared to cytisinicline.

### **Virtual Smoking Cessation KOL Roundtable to be Held November 17, 2020**

Achieve announced plans to host a virtual roundtable on cytisinicline and smoking cessation on Tuesday, November 17, 2020, at 12:00PM EST. Five esteemed experts in the field of smoking cessation will discuss the ongoing ORCA-2 trial, review recent cytisinicline data, and discuss the importance of smoking cessation in the midst of the COVID-19 pandemic. Visit <http://ir.achievelifesciences.com/events-and-webcasts> for additional information and [click here](#) to register for the event.

### **Financial Results**

As of September 30, 2020, the company's cash, cash equivalents, and restricted cash was \$22.4 million. Total operating expenses for the three and nine months ended September 30, 2020 were \$3.8 million and \$10.0 million, respectively. Total net loss for the three and nine months ended September 30, 2020 was \$3.8 million and \$10.0 million, respectively.

As of November 12, 2020, Achieve had 3,617,664 shares outstanding.

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### **Conference Call Details**

Achieve will host a conference call at 4:30pm Eastern time today, Thursday, November 12, 2020. 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) 472-9809 (U.S. & Canada) or (629) 228-0791 (International) and referencing conference ID 8047128. 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 U.S. annually.<sup>1,2</sup> 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.<sup>2</sup> 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.

### **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 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

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occurring after the date hereof, other than as may be required by applicable.

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**References**

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

<sup>2</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

Chantix® is a registered trademark of Pfizer Inc.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	1,891	1,824	4,535	7,911
General and administrative	1,863	1,893	5,494	5,408
Total operating expenses	<u>3,754</u>	<u>3,717</u>	<u>10,029</u>	<u>13,319</u>
Loss from operations	(3,754)	(3,717)	(10,029)	(13,319)
Other income (expense)	(10)	44	23	118
Net loss	<u>\$ (3,764)</u>	<u>\$ (3,673)</u>	<u>\$ (10,006)</u>	<u>\$ (13,201)</u>
Basic and diluted net loss per share	<u>\$ (1.14)</u>	<u>\$ (9.07)</u>	<u>\$ (4.55)</u>	<u>\$ (35.96)</u>
Weighted average number of basic and diluted common shares	<u>3,289,252</u>	<u>405,012</u>	<u>2,197,368</u>	<u>367,103</u>

**Consolidated Balance Sheets**  
(In thousands)

	<u>September 30,</u>	<u>December 31,</u>
	<u>2020</u>	<u>2019</u>
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 22,443	\$ 16,714
Prepaid expenses and other current assets	1,669	670
Property, equipment and other assets	358	244
Right-of-use assets	193	329
License agreement	1,920	2,087
Goodwill	1,034	1,034
Total assets	<u>\$ 27,617</u>	<u>\$ 21,078</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 1,719	\$ 2,666
Current portion of long-term obligations	129	203
Long-term obligations	94	159
Stockholders' equity	25,675	18,050
Total liabilities and stockholders' equity	<u>\$ 27,617</u>	<u>\$ 21,078</u>