
**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): March 13, 2020

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, 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:

<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 March 13, 2020, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2019. 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	<u>Press release of Achieve Life Sciences, Inc. dated March 13, 2020</u>

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: March 13, 2020

/s/ John Bencich

John Bencich
Chief Financial and Operating Officer



Achieve Reports Financial Results for Fourth Quarter and Year-End 2019 and Provides Update on Cytisinicline Development Program

SEATTLE, Wash and VANCOUVER, British Columbia, March 13, 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 fourth quarter and year-end 2019 financial results and provided an update on the cytisinicline clinical development program.

Recent Highlights

- Completed meeting with the U.S. Food & Drug Administration (FDA) to finalize the Phase 3 cytisinicline clinical development program
- Presented new findings from the Phase 2b ORCA-1 trial evaluating cytisinicline in U.S. smokers at the Society for Research on Nicotine & Tobacco (SRNT) Annual Conference in March 2020
- Established agreement with the FreeMind Group to assist in securing non-dilutive funding to evaluate cytisinicline in vapers and e-cigarette users
- Closed underwritten public offering for gross proceeds of \$13.8 million, before underwriting discounts and commissions and offering expenses

“With over 34 million smokers and nearly 11 million vape and e-cigarette users in the United States alone, the nicotine addiction epidemic continues to be a major public health crisis that Achieve is exclusively focused on addressing through the development of cytisinicline,” commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. “Our key priorities in the coming months are to initiate the ORCA-2 Phase 3 clinical trial in smokers and secure non-dilutive financing to evaluate cytisinicline specifically in the growing population of vape users.”

Completed FDA Meeting

In the fourth quarter of 2019, Achieve received feedback on the Phase 3 clinical trial protocols and the cytisinicline clinical development program. Specifically, the FDA agreed with the overall Phase 3 study designs that anticipate utilizing the simplified cytisinicline dosing schedule of 3.0 mg administered three times daily and the duration of 6 and 12 weeks of treatment. Additionally, the FDA agreed that no further escalation in cytisinicline dosing beyond the 30.0 mg dose was necessary for defining a maximum tolerated dose, which is required for the New Drug Application.

Additional ORCA-1 Results at SRNT Annual Conference

An oral presentation featuring new ORCA-1 Phase 2b trial analyses was presented at the SRNT Annual Meeting in March 2020. In addition to previously reported data indicating a statistically significant improvement in quit rates, new analyses demonstrate cytisinicline biochemical efficacy via measurement of serum cotinine as well as the previous carbon monoxide efficacy. Additionally, further analyses confirm that cytisinicline benefit was observed across all clinical sites, baseline characteristics, and attributes. Thus, regardless of trial site location, patient demographics, smoking history, or prior treatments, all subjects treated with cytisinicline showed similar smoking cessation benefit.



Agreement with the FreeMind Group to secure non-dilutive financing for vaping trials

Achieve retained the FreeMind Group, an international consulting firm dedicated to assisting life science organizations secure non-dilutive funding. Achieve and FreeMind will conduct a strategic assessment of potential non-dilutive funding opportunities from various public and private sources, followed by anticipated grant production and submission, to further the clinical development of cytisinicline in vaping or e-cigarette cessation.

Closed underwritten public offering for gross proceeds of \$13.8 million

In December 2019, Achieve announced the closing of an underwritten public offering that raised total gross proceeds of \$13.8 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses.

Financial Results

As of December 31, 2019, the company's cash, cash equivalents, and restricted cash was \$16.7 million. Total operating expenses for the fourth quarter and year ended December 31, 2019 were \$3.2 million and \$16.5 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2019 was \$3.2 million and \$16.4 million, respectively.

As of March 13, 2020 Achieve had 31,352,764 shares outstanding.

Conference Call Details

Achieve will host a conference call at 8:30 a.m. Eastern time today, Friday, March 13, 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 6628874. 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 and is responsible for more than eight million deaths annually worldwide. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking². 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.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor"

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

² Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1



provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the ability to secure any non-dilutive financing, the timing and nature of cytisinicline clinical development 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; 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.

Achieve Contact

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"ORCA is a trademark of Achieve Life Sciences, Inc."



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

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses:				
Research and development	1,763	2,081	9,674	5,868
General and administrative	1,446	1,628	6,854	6,945
Total operating expenses	<u>3,209</u>	<u>3,709</u>	<u>16,528</u>	<u>12,813</u>
Loss from operations	(3,209)	(3,709)	(16,528)	(12,813)
Other income (expense)	15	72	133	126
Net loss	<u>\$ (3,194)</u>	<u>\$ (3,637)</u>	<u>\$ (16,395)</u>	<u>\$ (12,687)</u>
Basic and diluted net loss per share	<u>\$ (0.30)</u>	<u>\$ (0.55)</u>	<u>\$ (1.99)</u>	<u>\$ (3.61)</u>
Weighted average number of basic and diluted common shares	<u>10,802,186</u>	<u>6,659,379</u>	<u>8,246,400</u>	<u>3,510,217</u>

Consolidated Balance Sheets
(In thousands)

	<u>December 31,</u>	<u>December 31,</u>
	<u>2019</u>	<u>2018</u>
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 16,714	\$ 14,654
Prepaid expenses and other current assets	670	933
Property, equipment and other assets	244	153
Right-of-use assets	329	—
License agreement	2,087	2,310
Goodwill	1,034	1,034
Total assets	<u>\$ 21,078</u>	<u>\$ 19,084</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 2,666	\$ 3,259
Current portion of long-term obligations	203	11
Long-term obligations	159	12
Stockholders' equity	18,050	15,802
Total liabilities and stockholders' equity	<u>\$ 21,078</u>	<u>\$ 19,084</u>