
**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 11, 2021

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 11, 2021, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 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 | <u>Press release of Achieve Life Sciences, Inc. dated March 11, 2021</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 11, 2021

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

Achieve Reports Financial Results for Fourth Quarter and Year-End 2020 and Provides Corporate Update

SEATTLE, Wash and VANCOUVER, British Columbia, March 11, 2021-- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation and nicotine addiction, today announced fourth quarter and year-end 2020 financial results and provided an update on the cytisine clinical development program.

Recent Events & Highlights

- Initiated the Phase 3 ORCA-2 clinical trial evaluating the efficacy and safety of 3 mg cytisine dosed 3 times daily compared to placebo in 750 adult smokers at 15 clinical sites in the United States
- Presented data on smoker and e-cigarette user attitudes and perceptions on quitting at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting on February 24, 2021
- Closed financing of \$17.3 million, prior to deducting underwriting discounts and commissions and estimated offering expenses, in December 2020
- Facilitated Smoking Cessation Key Opinion Leader Virtual Roundtable in November 2020

"We concluded 2020 in the best financial position since the Company's inception and with the Phase 3 ORCA-2 trial underway at 15 well-established smoking cessation research centers in the United States. As we look to the year ahead, our focus will continue to be on execution of this pivotal trial, completion of additional NDA-enabling activities, and exploration of new opportunities for expansion into additional populations, such as vaping and e-cigarette users, who may benefit from a new cessation therapeutic option like cytisine," commented John Bencich, Chief Executive Officer of Achieve.

Phase 3 ORCA-2 Trial

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 cytisine 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 cytisine 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 cytisine treatment arms show a statistical benefit compared to placebo. The trial is expected to complete enrollment by the middle of the 2021.

Data Highlighting Smoker Dissatisfaction with Available Treatments Presented at SRNT

Achieve data presented at the SRNT Annual Meeting in February 2021 provided insights into current and former smokers' perceptions on currently available cessation treatment options. In a survey of 1,122 individuals, overall satisfaction and perceived efficacy with available therapies was low, with the best performing treatment leading to satisfaction in less than one-third of the respondents. The study found a majority of prescription cessation medication users do not complete their full 3-month



course of therapy, with 53% reporting less than 1 month of use. Smokers reported side effects and lack of efficacy as the most common reason for discontinuation or lack of initiation with varenicline or bupropion.

Data Elucidating Vaping/e-Cigarette Users Behavior and Quitting Intentions Presented at SRNT

Two Achieve posters were presented at the SRNT Annual Meeting in February 2021 reporting findings from a survey of 508 users of nicotine vape products. The results showed that the primary reason to initiate e-cigarettes/vaping was to quit combustible cigarettes. While proven successful in the cohort of subjects who only utilize vape, dual users, those who vape but also continue to smoke, reported 2-times heavier nicotine use than their counterparts. Additionally, the data indicated that 73% of e-cigarette/vape users intend to quit vaping in the next 3-12 months. Of those who intend to do so in the next 3 months, more than half reported they would be “very/extremely likely to try a new prescription product” to help them quit.

Completed \$17.3 Million Financing in December 2020

In December 2020, Achieve announced the closing of an underwritten public offering of 2,472,500 shares of its common stock at a public offering price of \$7.00, for total gross proceeds of \$17.3 million, prior to deducting underwriting discounts and commissions and estimated offering expenses. This included the full exercise of the underwriter’s over-allotment option to purchase an additional 322,500 shares of common stock.

Virtual Smoking Cessation KOL Roundtable on November 17, 2020

Achieve hosted a virtual roundtable on cytisinicline and smoking cessation in November 2020. Five esteemed experts in the field of smoking cessation discussed the ongoing Phase 3 ORCA-2 trial, reviewed recent cytisinicline data, and presented evidence supporting the importance of smoking cessation in the midst of the COVID-19 pandemic.

Financial Results

As of December 31, 2020, the company’s cash, cash equivalents, and restricted cash was \$35.9 million. Total operating expenses for the fourth quarter and year ended December 31, 2020 were \$4.7 million and \$14.8 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2020 was \$4.7 million and \$14.7 million, respectively.

As of March 11, 2021, Achieve had 6,149,917 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30pm Eastern time today, Thursday, March 11, 2021. 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 9395238. 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.^{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 FDA for any indication in the U.S.

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 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 .



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>2020</u> | <u>2019</u> | <u>2020</u> | <u>2019</u> |
| Operating expenses: | | | | |
| Research and development | 2,347 | 1,763 | 6,882 | 9,674 |
| General and administrative | 2,374 | 1,446 | 7,868 | 6,854 |
| Total operating expenses | <u>4,721</u> | <u>3,209</u> | <u>14,750</u> | <u>16,528</u> |
| Loss from operations | (4,721) | (3,209) | (14,750) | (16,528) |
| Other income (expense) | (3) | 15 | 20 | 133 |
| Net loss | <u>\$ (4,724)</u> | <u>\$ (3,194)</u> | <u>\$ (14,730)</u> | <u>\$ (16,395)</u> |
| Basic and diluted net loss per share | <u>\$ (1.11)</u> | <u>\$ (5.91)</u> | <u>\$ (5.42)</u> | <u>\$ (39.76)</u> |
| Weighted average number of basic and diluted common shares | <u>4,266,432</u> | <u>540,109</u> | <u>2,718,909</u> | <u>412,320</u> |

Consolidated Balance Sheets
(In thousands)

| | <u>December 31,</u> | <u>December 31,</u> |
|--|---------------------|---------------------|
| | <u>2020</u> | <u>2019</u> |
| Assets: | | |
| Cash, cash equivalents and restricted cash | \$ 35,903 | \$ 16,714 |
| Prepaid expenses and other current assets | 1,122 | 670 |
| Property, equipment and other assets | 229 | 244 |
| Right-of-use assets | 146 | 329 |
| License agreement | 1,864 | 2,087 |
| Goodwill | 1,034 | 1,034 |
| Total assets | <u>\$ 40,298</u> | <u>\$ 21,078</u> |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued liabilities | \$ 2,843 | \$ 2,666 |
| Current portion of long-term obligations | 92 | 203 |
| Long-term obligations | 77 | 159 |
| Stockholders' equity | <u>37,286</u> | <u>18,050</u> |
| Total liabilities and stockholders' equity | <u>\$ 40,298</u> | <u>\$ 21,078</u> |