
**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): May 14, 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 May 14, 2020, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 5.07 Submission of Matters to a Vote of Security Holders.

The Annual Meeting of Stockholders of the Company was held on May 12, 2020. The following is a brief description of each matter voted upon and the certified voting results.

- (1) Election of seven directors to serve until the Company’s next annual meeting or until the directors’ successors are duly elected and qualified:

	<u>For</u>	<u>Withhold</u>	<u>Broker Non-Votes</u>
Anthony Clarke	6,756,706	1,406,912	15,161,787
Scott Cormack	6,729,779	1,433,839	15,161,787
Donald Joseph	6,722,921	1,440,697	15,161,787
Martin Mattingly	6,954,521	1,209,097	15,161,787
Jay Moyes	6,737,294	1,426,324	15,161,787
Stewart Parker	6,910,194	1,253,424	15,161,787
Richard Stewart	6,773,709	1,389,909	15,161,787

Pursuant to the foregoing votes, the nominees listed above were elected as directors to serve on the Company’s board of directors.

- (2) Ratification of the appointment of PricewaterhouseCoopers LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2020:

<u>For</u>	<u>Against</u>	<u>Abstain</u>	<u>Broker Non-votes</u>
19,519,689	3,311,533	494,183	—

Pursuant to the foregoing votes, the appointment of PricewaterhouseCoopers LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2020 was ratified.

- (3) Approval of an amendment to the Company’s Certificate of Incorporation, as amended, to effect a reverse stock split by a ratio not to exceed 1-for-20:

<u>For</u>	<u>Against</u>	<u>Abstain</u>	<u>Broker Non-votes</u>
15,892,238	7,376,787	56,380	—

Pursuant to the foregoing votes, this matter was approved.

(4) Approval of an amendment of the Company's 2018 Equity Incentive Plan to increase the number of shares available for issuance thereunder:

For	Against	Abstain	Broker Non-votes
5,126,941	2,926,614	110,063	15,161,787

Pursuant to the foregoing votes, this matter was approved.

(5) Approval, by a non-binding advisory vote, the compensation paid by the Company to its Named Executive Officers:

For	Against	Abstain	Broker Non-votes
5,795,068	2,205,275	163,275	15,161,787

Pursuant to the foregoing votes, this matter was approved.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Achieve Life Sciences, Inc. dated May 14, 2020

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: May 14, 2020

/s/ John Bencich

John Bencich
Chief Financial and Operating Officer

Achieve Reports Financial Results for First Quarter 2020 and Provides Update on Cytisinicline Development Program

SEATTLE, Wash and VANCOUVER, British Columbia, May 14, 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 first quarter 2020 financial results and provided an update on the cytisinicline clinical development program.

Recent Highlights

- Submitted required non-clinical supportive data for longer cytisinicline treatment to the U.S. Food & Drug Administration (FDA) in preparation for Phase 3 cytisinicline ORCA-2 trial initiation
- Closed financing for gross proceeds of approximately \$1.9 million, prior to deducting placement agent commissions and estimated offering expenses
- 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
- Established agreement with the FreeMind Group to assist in securing non-dilutive funding to evaluate cytisinicline in vapers and e-cigarette users

“The COVID-19 pandemic has revealed an increased risk for smokers due to the known relationship between smoking and respiratory illnesses and we see an even greater need to do all that we can to help them quit,” commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. “We expect to initiate the 750 patient Phase 3 ORCA-2 trial in the second-half of 2020, subject to financing and the ability to conduct the trial safely in light of the COVID-19 pandemic.”

Completed FDA Submission

In preparation for initiation of the Phase 3 ORCA-2 clinical trial of cytisinicline, the Company has now submitted to FDA all requested non-clinical data to allow 6 and 12 weeks of cytisinicline treatment in the Phase 3 trials. No new safety or toxicology signals were observed in the non-clinical data evaluating either 13 or 26 weeks of cytisinicline treatment.

Closed private placement financing for gross proceeds of \$1.9 million

In April 2020, Achieve announced it entered into definitive agreements for a private placement of its securities for gross proceeds of approximately \$1.9 million, prior to deducting placement agent commissions and estimated offering expenses. The Company intends to use the proceeds to fund clinical research and development, and for general working capital.

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

In the first quarter of 2020, Achieve retained the FreeMind Group, an international consulting firm dedicated to assisting life science organizations secure non-dilutive funding. Achieve and FreeMind are conducting 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.

Financial Results

As of March 31, 2020, the company's cash, cash equivalents, and restricted cash was \$12.2 million. Total operating expenses for the quarter ended March 31, 2020 were \$3.4 million. Total net loss for the quarter ended March 31, 2020 was \$3.3 million.

As of March 14, 2020, Achieve had 37,515,408 shares outstanding.

Conference Call Details

Achieve will host a conference call at 8:00 a.m. Eastern time today, Thursday, May 14, 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 4477265. 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" 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

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



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.

Achieve Contact

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

	Three months ended March 31,	
	2020	2019
Operating expenses:		
Research and development	1,541	4,055
General and administrative	1,816	1,885
Total operating expenses	3,357	5,940
Loss from operations	(3,357)	(5,940)
Other income (expense)	37	36
Net loss	\$ (3,320)	\$ (5,904)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.88)
Weighted average number of basic and diluted common shares	30,936,777	6,721,184

Consolidated Balance Sheets
(In thousands)

	March 31, 2020	December 31, 2019
	Assets:	
Cash, cash equivalents, short term investments and restricted cash	\$ 12,206	\$ 16,714
Prepaid expenses and other current assets	746	670
Property, equipment and other assets	345	244
Right-of-use assets	285	329
License agreement	2,031	2,087
Goodwill	1,034	1,034
Total assets	\$ 16,647	\$ 21,078
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 1,348	\$ 2,666
Current portion of long-term obligations	196	203
Long-term obligations	118	159
Stockholders' equity	14,985	18,050
Total liabilities and stockholders' equity	\$ 16,647	\$ 21,078