
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 15, 2019

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 Street, Suite 1030, Vancouver,
B.C. V6E 4H1
(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 Instructions 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))

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.

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

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2019, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2019. 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 14, 2019. 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	817,595	18,645	3,599,309
Scott Cormack	813,143	23,097	3,599,309
Donald Joseph	816,199	20,041	3,599,309
Martin Mattingly	817,439	18,801	3,599,309
Jay Moyes	816,917	19,323	3,599,309
Stewart Parker	817,038	19,202	3,599,309
Richard Stewart	816,771	19,469	3,599,309

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, 2019:

<u>For</u>	<u>Against</u>	<u>Abstain</u>	<u>Broker Non-votes</u>
4,315,679	62,437	57,433	—

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, 2019 was ratified.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Achieve Life Sciences, Inc. dated May 15, 2019

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 15, 2019

/s/ John Bencich

John Bencich
Chief Financial and Operating Officer



Achieve Reports Financial Results for First Quarter 2019 and Provides Cytisinicline Clinical Development Update

SEATTLE, Wash and VANCOUVER, British Columbia, May 15, 2019-- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today provided an update on the cytisinicline clinical development program and announced first quarter 2019 financial results.

ORCA-1 Trial Status

Achieve's 254-subject Phase 2b ORCA-1 trial of cytisinicline in U.S. smokers completed enrollment in February. The Company announced recently that the last study visit for the last subject enrolled in the ORCA-1 trial has occurred. The trial is evaluating cytisinicline in both the 1.5 mg and 3.0 mg doses on a declining titration schedule as well as three times daily dosing, both over 25 days. The primary efficacy endpoint is reduction in the number of cigarettes smoked during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 topline efficacy and safety data are expected to be announced by the end of the second quarter.

Maximum Tolerated Dose (MTD) Trial Extension

Achieve recently initiated a trial to assess the MTD for a single administered oral dose of cytisinicline in smokers. The starting dosage of cytisinicline was 6 mg and is increased in separate groups of subjects for each escalated dose level until stopping criteria, based on the occurrence of dose-limiting adverse events, are reached. To date, 21 mg cytisinicline has been evaluated without evidence of dose limiting toxicity. The trial's Data Safety Monitoring Committee has recommended a protocol amendment to evaluate additional higher doses of cytisinicline.

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, "With the results of the ORCA-1 trial expected by the end of the second quarter, we are rapidly approaching another critical milestone for the cytisinicline development program. Importantly, as confirmed by the tolerability of high dose levels in our MTD study, we believe cytisinicline may offer a differentiated and new treatment option for the millions of people who are battling nicotine addiction."

Financial Results

As of March 31, 2019, the company's cash, cash equivalents, short-term investments and restricted cash were \$9.7 million. Each of total operating expenses and net loss for the first quarter of 2019 were \$5.9 million.

As of May 15, 2019 Achieve had 6,865,950 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 p.m. Eastern time today, Wednesday, May 15, 2019. 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 6973659. 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 nearly seven 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 epidemic through the development and commercialization of cytisnicline.

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 cytisnicline 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 planned cytisnicline clinical development activities, the timing of clinical development activities related to cytisnicline, expectations from current data, expectations regarding when trial data may be reported, the potential market size for cytisnicline and the potential benefits of cytisnicline. 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 cytisnicline 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 cytisnicline; the risk that cytisnicline 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."

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

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



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

	Three months ended March 31,	
	2019	2018
Operating expenses:		
Research and development	4,055	1,201
General and administrative	1,885	1,813
Total operating expenses	5,940	3,014
Loss from operations	(5,940)	(3,014)
Other income (expense)	36	(8)
Net loss before income taxes	\$ (5,904)	\$ (3,022)
Recovery of deferred income taxes	—	—
Net loss	<u>\$ (5,904)</u>	<u>\$ (3,022)</u>
Basic and diluted net loss per share	<u>\$ (0.88)</u>	<u>\$ (2.43)</u>
Weighted average number of basic and diluted common shares	<u>6,721,184</u>	<u>1,243,149</u>

Consolidated Balance Sheets
(In thousands)

	March 31,	December 31,
	2019	2018
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 9,715	\$ 14,654
Prepaid expenses and other current assets	866	933
Property, equipment and other assets	177	153
Operating lease right-of-use assets	455	—
License agreement	2,254	2,310
Goodwill	1,034	1,034
Total assets	<u>\$ 14,501</u>	<u>\$ 19,084</u>
Liabilities and stockholders' equity:		
Warrant Liability	—	—
Current portion of long-term obligations	16	11
Current portion of long-term lease liability	170	—
Long-term obligations	24	12
Long-term lease liability	289	—
Stockholders' equity	10,189	15,802
Total liabilities and stockholders' equity	<u>\$ 14,501</u>	<u>\$ 19,084</u>