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): June 11, 2019

ACHIEVE LIFE SCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**033-80623**	**95-4343413**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1	**V6E 4H1**
(Address of Principal Executive Offices)	**(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
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 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 8.01. Other Events.

On June 11, 2019, Achieve Life Sciences, Inc. (the "Company") issued a press release attached hereto as Exhibit 99.1 and incorporated by reference herein reporting statistically significant improvement in quit rates for its simplified cytisinicline dosing schedule in Phase 2b of the Company's ORCA-1 dose-selection trial.

Item 9.01. Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press release dated June 11, 2019.

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: June 11, 2019

/s/ John Bencich
John Bencich
Chief Financial and Operating Officer

Exhibit 99.1

Achieve Life Sciences Announces Statistically Significant Improvement in Quit Rates for Simplified Cytisinicline Dosing Schedule in Phase 2b ORCA-1 Dose-Selection Trial

3.0 mg, 3 times daily selected as dose for future clinical development

SEATTLE, Wash. and VANCOUVER, British Columbia, June 11, 2019 — Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company focused on nicotine addiction, today announced positive results from the ORCA-1 dose-selection trial of cytisinicline for smoking cessation. The outcome of the 254-subject, ORCA-1 trial is the selection of 3.0 mg, three times daily (TID) for Phase 3 development.

The primary endpoint was the reduction in daily smoking, a self-reported measure. Three of the four cytisinicline treatment arms demonstrated a statistically significant improvement, as defined in the protocol as $p < 0.05$, compared to placebo. The fourth arm trended to significance ($p= 0.052$). Across all treatment arms, over the 25-day treatment period, subjects on cytisinicline experienced a 74-80% median reduction in the number of cigarettes smoked, compared to a 62% reduction in the placebo arms.

The secondary endpoint of the trial was a 4-week continuous abstinence rate, which is the relevant endpoint for regulatory approval. Cytisinicline treatment showed significant improvements in abstinence rates compared to placebo. The most impressive results were observed in the 3 mg TID treatment arm which demonstrated a 54% abstinence rate at week 4, compared to 16% for placebo ($p < 0.0001$) and a continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline compared to 8% for placebo ($p= 0.005$).

All four cytisinicline arms demonstrated statistically significant ($p < 0.05$) reductions in expired carbon monoxide (CO), a biochemical measure of smoking activity. Expired CO levels declined by a median of 71-80% in the cytisinicline treatment arms, compared to only 38% in the placebo arms. The lack of consistency in the reduction of expired CO levels compared to the self-reported data suggest potential under-reporting of cigarettes smoked by subjects on placebo.

“The robust efficacy results in the simplified, three times daily dosing arms exceeded our expectations, particularly, the statistically significant abstinence rates. This is of importance given that a continuous abstinence rate is the endpoint for regulatory approval in smoking cessation trials,” said Rick Stewart, Chairman and CEO of Achieve. “In addition to efficacy, the cytisinicline safety data observed in ORCA-1 reflects the historically strong safety profile already experienced in Central and Eastern Europe.”

Adherence to study treatment was greater than 98.5% across all arms and cytisinicline was well-tolerated with no serious adverse events reported. The most commonly reported (>5%) adverse events (AEs) across all cytisinicline treatment arms versus placebo were abnormal dreams, insomnia, upper respiratory tract infections, and nausea. In the 3 mg TID treatment arm versus placebo, the most common AEs were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%).

The Company expects to conduct further analyses of the ORCA-1 trial and submit data for presentation at a future medical meeting. Additionally, Achieve plans to discuss the trial's outcome with the FDA and finalize Phase 3 protocol details in the second-half of 2019.

Achieve would like to thank the investigators, healthcare providers, and subjects whose commitment and efforts to ORCA-1 made this trial a success. Additional information on cytisinicline and the ORCA program can be found at www.achievelifesciences.com and www.orcaprogram.com.

Conference Call Details

Achieve will host a conference call at 8:30 a.m. Eastern time today, Tuesday, June 11, 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 6986745. A webcast replay will be available approximately two hours after the call and will be archived on the website for 90 days.

About Cytisinicline

Tobacco use is currently the leading cause of preventable death and is responsible for nearly seven million deaths annually worldwide[1]. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking[2]. Achieve's focus is to address the global smoking health 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.

About ORCA-1

ORCA-1 is the first in Achieve's ORCA (**O**ngoing **R**esearch of **C**ytisinicline for **A**ddiction) Program, which aims to evaluate the safety and effectiveness of cytisinicline for smoking cessation and potentially other addiction indications. The study was designed to evaluate the declining titration schedule, currently utilized in Central and Eastern Europe, compared to a simplified TID schedule at both the 1.5 mg and 3 mg cytisinicline doses compared to placebo. Subjects were provided face-to-face behavioral support over the full course of the study. Smoking abstinence was measured at week 4 (end-of-treatment). Continuous abstinence was also measured at weeks 5 through 8(end-of-study). Abstinence assessments were verified by expired carbon monoxide (CO), a biochemical measure of smoking activity.

The study was blinded to dosing. Demographics were similar between schedules and for treatment arms in gender, age, years of prior smoking, and number of previous quit attempts. At baseline, subjects in the study reported smoking a median of 20 cigarettes per day. ORCA-1 was initiated in October 2018 and enrolled 254 smokers at eight centers across the United States.

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 cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, the potential market size for cytisinicline and the potential benefits of cytisinicline. 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 law.

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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