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): September 28, 2018

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.)**

1001 W. Broadway, Suite 400 **Vancouver, BC** **(Address of Principal Executive Offices)**	**V6H 4B1** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (604)736-3678

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))

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 8.01 Other Events.

On September 27, 2018, Achieve Life Sciences, Inc. (the "Company") announced results of a clinical study demonstrating similar bioavailability for a new cytisine formulation in fed and fasted subjects.

On September 18, 2018, the Company announced that the International Journal of Drug Policy published data demonstrating superior cytisine abstinence rates compared to nicotine replacement therapy.

Copies of the related press releases are filed as Exhibits 99.1 and 99.2 hereto and are incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Achieve Life Sciences, Inc. dated September 27, 2018
99.2	Press release of Achieve Life Sciences, Inc. dated September 18, 2018

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: September 28, 2018

/s/ John Bencich
John Bencich
Chief Financial Officer

Achieve Announces Results of Clinical Study Demonstrating Similar Bioavailability for a New Cytisine Formulation in Fed and Fasted Subjects

SEATTLE, Wash and VANCOUVER, British Columbia, Sept. 27, 2018— Achieve Life Sciences, Inc. (NASDAQ: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, today announced results of a clinical study evaluating the effect of food on the bioavailability of a new formulation for cytisine.

The study evaluated the bioavailability of a new formulation of 3 mg cytisine under fed and fasted conditions in 12 healthy volunteer smokers. Study results demonstrated bioequivalence when cytisine was administered with or without food. Cytisine was extensively absorbed after oral administration with maximum cytisine concentration levels observed in the blood within less than two hours with or without food. Total excretion levels of cytisine also remained equivalent in both the fed and fasted states, and the 3 mg dose of this new formulation of cytisine was very well tolerated. These results are similar to results evaluating the previous cytisine formulation for bioavailability under fed and fasted conditions in 24 healthy, non-smoking volunteers.

“We believe this new cytisine formulation will allow for an extended shelf-life and will be used in the upcoming Phase 2b clinical trial as well as the Phase 3 clinical program,” said Rick Stewart, Chairman and CEO of Achieve. “We are pleased with the similar results regarding this new formulation in smokers and that the higher dose of 3 mg cytisine continues to demonstrate a good safety profile with or without food.”

Cytisine is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 20 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand.

About Cytisine

Achieve’s focus is to address the global smoking health epidemic through the development and commercialization of cytisine. Tobacco use is currently the leading cause of preventable death and is

responsible for nearly six million deaths annually worldwide[1]. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking[2].

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. Two prior, large-scale Phase 3 clinical studies of cytisine, with favorable outcomes, have been successfully completed in over 2,000 patients. The TASC trial was a 740 patient, double-blind, placebo controlled trial conceived by Professor Robert West at University College London and funded by the U.K. National Prevention Research Initiative. The CASCAID trial was a 1,310 patient, single-blind, non-inferiority trial comparing cytisine to nicotine replacement therapy (NRT). The CASCAID trial was conceived by Dr. Natalie Walker, National Institute for Health Innovation, University of Auckland and funded by the Health Research Council of New Zealand. Both trials were published in the New England Journal of Medicine.

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 cytisine clinical development activities, the potential market size for cytisine and the potential benefits of cytisine. 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 cytisine 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 cytisine; the risk that cytisine 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.

Achieve Contact

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(415) 375-3340 ext. 4

[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011, Geneva: World Health Organization, 2011.
[2] Annals of Epidemiology , Volume 25 , Issue 3 , 179 – 182.e1

Achieve Announces Positive Cytisine Data Published in International Journal of Drug Policy

Cytisine Demonstrated Superior Abstinence Rates Compared to Nicotine Replacement Therapy

SEATTLE, Wash. and VANCOUVER, British Columbia, Sept. 18, 2018— Achieve Life Sciences, Inc. (NASDAQ: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, today announced the publication of new cytisine data from an independent observational study in the International Journal of Drug Policy.

The observational study compared the effectiveness of cytisine and nicotine replacement therapy (NRT) as an aid to smoking cessation in the Russian Federation. Evaluation of 301 subjects who had used either cytisine or NRT determined that smokers in the cytisine group were approximately three times more likely to achieve 90-days abstinence compared to those who attempted to quit with NRT (p=0.011). As demonstrated in prior cytisine studies, the highest abstinence rates were observed in subjects who also received smoking cessation behavioral support and counseling. Cytisine was found to be well tolerated. The authors concluded the findings support previous trial evidence indicating that cytisine is superior to NRT for achieving short- and long-term abstinence and should be considered a first-line pharmacologic treatment for smoking cessation.

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, “These data provide further real-world evidence on the important role cytisine can play in helping smokers quit. Cytisine has been commercially available in numerous countries in Central and Eastern Europe for decades and our mission is to make it a globally available treatment option for people battling nicotine addiction.”

The full article *“The effectiveness of Cytisine versus Nicotine Replacement Treatment for Smoking cessation in the Russian Federation”* can be accessed by visiting https://www.ijdp.org/article/S0955-3959(18)30161-0/fulltext.

About the Study

Study data were obtained from the 2009 Russian Global Adult Tobacco Survey of more than 11,000 individuals. The observational study utilized cross-sectional data to compare self-reported 30-day and 90-day smoking abstinence rates of smokers who used either cytisine or NRT as an aid to smoking cessation. This analysis evaluated 301 subjects, including 88 in the cytisine arm and 186 in the NRT arm. Subjects who utilized combination methods or pharmacotherapy in the prior year were not included in the analysis.

About Achieve & Cytisine

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