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): August 10, 2017

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	V6H 4B1
(Address of Principal Executive Offices)	(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:

☐ 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 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 7.01 Regulation FD Disclosure

The Company has issued a press release on August 10, 2017 entitled "Achieve Announces FDA Acceptance of the Investigational New Drug Application (IND) for Cytisine as a Smoking Cessation Treatment," which is attached as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities and Exchange Act of 1934, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on August 10, 2017

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: August 10, 2017

/s/ John Bencich
John Bencich
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued August 10, 2017

Exhibit 99.1

Achieve Announces FDA Acceptance of the Investigational New Drug Application (IND) for Cytisine as a Smoking Cessation Treatment

Strategic Collaboration with the National Institutes of Health (NIH) Instrumental in Facilitating IND-enabling Studies

BOTHELL, Wash and VANCOUVER, British Columbia, Aug. 10, 2017— Achieve Life Sciences, Inc. (NASDAQ: ACHV) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for cytisine, an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 15 years. The company is now authorized to proceed with clinical development of cytisine in the U.S.

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,100 patients in Phase 3 clinical trials conducted in Europe and New Zealand. Achieve expects to commence a Phase 3 trial of cytisine in the United States in the first-half of 2018.

“FDA acceptance of the cytisine IND represents a significant milestone for Achieve, providing further validation of our objective to obtain FDA approval for cytisine and bring this important therapy to people battling nicotine and tobacco addition,” said Rick Stewart, Chairman and CEO of Achieve. “We are extremely grateful for the support and commitment we have received from the National Institutes of Health (NIH), which has sponsored a number of non-clinical studies to enable our IND submission.”

According to the U.S. Surgeon General’s 2014 report[1] “The Health Consequences of Smoking - 50 years of Progress”, there are more than 16 million Americans living with diseases caused by smoking and it is responsible for more than 480,000 deaths per year. The report states that productivity losses from premature death exceed $150 billion per year and the annual costs of direct medical care of adults attributable to smoking are estimated to be over $130 billion.

“Given the burden of smoking-related illnesses, cytisine could be a potential drug of public health importance. NCCIH efforts in collaboration with the NIH Blueprint Neurotherapeutics Network, and the National Cancer Institute Developmental Therapeutics Program, have contributed to our understanding of cytisine’s safety profile, which is needed for clinical development. With further clinical testing, if cytisine is approved by the FDA, another smoking cessation option would be available to help reduce the number of lives lost due to tobacco smoking and nicotine addiction,” said David Shurtleff, Ph.D., NCCIH deputy director.

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.

References:

1. **https://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf**

About Achieve and Cytisine

Achieve is developing cytisine as a smoking cessation aid. Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe for more than 15 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,000 patients in Phase 3 clinical trials conducted in Europe and New Zealand. Achieve's focus is to address the global smoking health epidemic, which is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide. Discussions have been held with FDA and European regulatory agencies to determine the clinical and regulatory pathway towards making cytisine widely available.

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 of clinical development of cytisine, the 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 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 the final Proxy Statement/Prospectus/Information Statement filed pursuant to Rule 424(b)(3) in connection with Achieve's recent merger, and 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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