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): October 22, 2020

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, 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:

☐ 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(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value 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 7.01. Regulation FD Disclosure.

On October 22, 2020, Achieve Life Sciences, Inc. (the "Company") issued a letter to its shareholders (the "Shareholder Letter"). A copy of the Shareholder Letter is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Shareholder Letter will also be available for viewing at the Company's investor website. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in this Item 7.01 of Current Report on Form 8-K, as well as Exhibit 99.1, shall not be treated as "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Shareholder Letter, dated October 22, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Achieve Life Sciences, Inc.

Date: October 22, 2020

/s/ John Bencich

John Bencich
Chief Executive Officer

Exhibit 99.1

October 22, 2020

Dear Fellow Shareholders,

We hope this letter finds you and your families safe and healthy. Given that we continue to live in unprecedented times, faced with uncertainty and unique challenges, John and I thought it was appropriate to reach out with an update on the company's progress.

Achieve remains committed to prioritizing the health and safety of our patients, health care providers, and employees. Like many of you, we have adjusted how we conduct business. Our teams continue to work remotely, we have restricted all non-essential travel, and we have implemented numerous safeguards for employees and stakeholders. This commitment extends to participants in our upcoming trials to mitigate against the potential impact of COVID-19. While this is not business as usual, we continue to make excellent progress advancing cytisinicline towards U.S. market approval.

On the corporate development front, we recently announced management changes that included internal promotions of two key executives. These changes have been planned for a long time and were expedited in part by the pandemic, which has restricted international travel for Rick Stewart and Dr. Anthony Clarke, co-founders of Achieve, who are both based in the United Kingdom.

The appointment of John Bencich as Chief Executive Officer and Dr. Cindy Jacobs as President and Chief Medical Officer reflects their contributions to the success of the company thus far. Rick Stewart will continue to serve as the Executive Chairman of the Board of Directors. Additionally, Rick will continue providing his expertise and leadership on strategic initiatives for the company, such as potential commercial partnering and registration of cytisinicline in European markets.

Over the last three years as Achieve's Chief Financial and Operating Officer, John has led the financing activities which provided the capital to complete the successful Phase 2 ORCA-1 trial last year, and more recently, the funding to allow us to initiate the Phase 3 ORCA-2 trial. John has consistently demonstrated his leadership capabilities across all aspects of the business and has been instrumental in ensuring that Achieve continues to execute on its key objectives.

Under her stewardship, Dr. Cindy Jacobs has led the clinical development team at Achieve and has been responsible for the successful ORCA-1 Phase 2b trial and the planning and execution of the ORCA-2 Phase 3 trial that recently commenced.

While our leadership has realigned, our management team remains steadfast in our mission and in our conviction that cytisinicline has great promise to change the lives of millions of smokers.

In this regard, we are pleased to have recently announced the start of the Phase 3 ORCA-2 trial that we expect will enroll 750 smokers at 15 clinical trial locations throughout the United States. ORCA-2 is the first randomized, double-blind Phase 3 trial evaluating a new therapy for smoking cessation in over a decade. ORCA-2 is designed to evaluate the efficacy and safety of 3 mg cytisinicline given three times daily for 6 and 12-weeks compared to placebo. Importantly, the study will be considered successful if either or both of the arms show an efficacy benefit.

As a reminder, the Phase 2b ORCA-1 trial that we conducted in 250 U.S. smokers showed robust efficacy and a well-tolerated safety profile for cytisinicline, providing important insights to help us to optimize the design of the Phase 3 trial. In ORCA-2, we will evaluate the higher 3 mg dose for a longer treatment duration and utilize the simplified three times daily dosing regimen. We believe these modifications could lead to potentially increased quit rates and more durable efficacy results.

The confidence that we have in cytisinicline's ability to help smokers quit comes not only from our own studies but from numerous clinical trials that have evaluated more than 10,000 smokers and have been conducted by external experts in the field of smoking cessation.

Most recently, the results of the "RAUORA" trial that compared cytisinicline to Chantix®, the market leader in smoking cessation, were presented at the Society for Research on Nicotine and Tobacco (SRNT) Annual European Meeting. This was the first-ever head-to-head study comparing these two treatments and enrolled a total of 679 smokers. The trial met its primary endpoint of showing that cytisinicline was non-inferior to Chantix and also showed a trend towards superiority for cytisinicline. Smokers who received cytisinicline **were one- and one-half times more likely to have quit smoking at six months** compared to those who received Chantix. Importantly, subjects on cytisinicline experienced **significantly fewer side effects, including significantly less nausea** than those subjects treated with Chantix.

Data were also presented at this meeting that may help to explain why the mechanism of action is directly implicated in the differentiated side effect profiles of these two smoking cessation medications. Research from the University of Cambridge Department of Biochemistry elucidated the potential role of the 5-HT3 receptor activity in the development of Chantix side effects. By comparison to cytisinicline, this study showed that Chantix has a 2000-greater fold binding affinity to the 5-HT3 receptor, which is believed to be the cause of increased rates of nausea and vomiting that smokers can experience while on Chantix.

It is widely documented that nicotine is one of the most addictive substances on the planet. Quitting smoking successfully often takes multiple attempts, which is why a new therapy with improved safety and tolerability is urgently needed. We believe and expect to confirm in our Phase 3 trials that cytisinicline can offer smokers a safe and effective new treatment and a renewed hope in their ability to quit.

As we look to the future, our primary focus is enrollment and execution of our Phase 3 program in smoking cessation. We do, however, continue to explore opportunities for expansion into new therapeutic indications, digital health technologies, and audiences who may benefit from cytisinicline, specifically, users of vapes or e-cigarettes.

The use of e-cigarettes continues to grow, with most recent reports indicating nearly 14 million adult users in the United States alone. While e-cigarettes have been historically viewed as less harmf ul than combustible cigarettes, their long-term safety remains controversial. In a recent study that we conducted surveying approximately 500 users of nicotine vaping devices or e-cigarettes, approximately 73% of participants responded they intend to quit vaping within the next 3 to 12 months. Of those who intended to quit even sooner, within the next three months, more than half stated they would be **extremely likely to try a new prescription product** to help them do so.

In partnership with leading smoking cessation and nicotine addiction experts, we have completed the development of a Phase 2 ORCA-V1 trial protocol to evaluate cytisinicline in this rapidly growing population of e-cigarette users. We are currently pursuing non-dilutive funding sources to help support this initiative. We believe that cytisinicline could be the first prescription drug to offer a new option for vape and e-cigarette users who are ready to quit their nicotine addiction for good.

Regarding our capitalization, our current funding and cash position are strong. We had approximately $12.2 million as of June 30, 2020, and secured an additional $14.8 million in proceeds, after commissions and offering expenses, from equity financings and warrant exercises during the third quarter. To that end, we recently terminated our At the Market (ATM) Offering Agreement with H.C. Wainwright & Co., LLC, as we did not expect to utilize the facility going forward. The facility was terminated unused with no shares issued or sold.

In closing, thank you for your interest and continued support of Achieve. This is an exciting time for the company as we embark on our Phase 3 program that has the potential to impact the health and well-being of millions of smokers. We will continue to remain focused on our mission and appreciate your support as we make the important transition to Phase 3 development.

Sincerely,

Rick Stewart
Executive Chairman

John Bencich
Chief Executive Officer

Forward Looking Statements

This letter 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, the timing and nature of cytisinicline clinical development activities, the potential market size for cytisinicline, the effectiveness and potential uses and benefits of cytisinicline, including but not limited to as an e-cigarette cessation product, and statements regarding the ability to secure any non-dilutive financing. 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 cytisinicline may not be effective in treating a larger breadth of diseases and addictions; 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; impacts from the COVID-19 pandemic, including but not limited to impacts on Achieve’s ongoing and planned clinical trials; 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.

Chantix® is a registered trademark of Pfizer, Inc.