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): November 6, 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., Canada 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 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 2.02 Results of Operations and Financial Condition.

On November 6, 2019, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Achieve Life Sciences, Inc. dated November 6, 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: November 6, 2019

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

Exhibit 99.1

Achieve Reports Financial Results for Third Quarter 2019 and Provides Update on Cytisinicline Development Program

SEATTLE, Wash and VANCOUVER, British Columbia, November 6, 2019-- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today provided an update on the cytisinicline clinical development program and announced third quarter 2019 financial results.

Q3 2019 Highlights

- Announced extension of a strategic collaboration with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH). As part of the collaboration, the NIH is funding and providing research efforts to conduct additional non-clinical development as requested by the FDA to support cytisinicline's New Drug Application (NDA).
- Presented positive efficacy and compliance results from the Phase 2b ORCA-1 dose-selection trial evaluating cytisinicline in 254 smokers at the Society for Research on Nicotine & Tobacco Europe (SRNT-E) 19th Annual Conference. Cytisinicline demonstrated a statistically significant improvement in quit rates for a simplified 3.0 mg, three times daily dose and was well-tolerated with no serious adverse events reported.
- Hosted Company's first Investor Day, including roundtable discussion with smoking cessation medical experts and presentation of final ORCA-1 data, including plans for Phase 3 development program.
- Presented at the H.C. Wainwright 21st Annual Global Investment Conference and the Ladenburg Thalmann 2019 Healthcare Conference.

"It has been a busy and eventful quarter with progressive data analysis further reinforcing the strength of the ORCA-1 Phase 2b trial and the potential for cytisinicline as a new treatment for the millions of people who are battling nicotine addiction," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. "Our key priority in the fourth quarter is to advance the ongoing, extensive preparations for the Phase 3 clinical trials, including our upcoming meeting with the FDA to finalize the cytisinicline Phase 3 protocols."

Extended Collaboration with NIH

In July, Achieve announced an extension of its strategic collaboration with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH). Under the extended collaboration, the NIH is funding and providing research efforts to conduct additional non-clinical studies as requested by the U.S. Food and Drug Administration (FDA) to be included in a cytisinicline New Drug Application (NDA). In discussions with the FDA in 2018, it was determined that a Good Laboratory Practice (GLP) non-clinical reproductive study would be required to support the NDA submission. NCCIH has agreed to sponsor this study which is expected to complete in 2020. In total, the NIH has committed approximately $6 million dollars to the development of cytisinicline.

Presented Final ORCA-1 Data at SRNT-E Conference

Achieve's Chief Scientific Officer, Dr. Anthony Clarke, facilitated two oral presentations featuring data from the Phase 2b ORCA-1 trial at the SRNT-E Annual Conference in Oslo. The ORCA-1 trial of cytisinicline in 254 U.S. smokers demonstrated a statistically significant improvement in quit rates for the 3.0 mg, three times daily dosing (TID) schedule. In the 3.0 mg TID arm, a 54% abstinence rate at week 4, compared to 16% for placebo ($p < 0.0001$) was observed. Continuous abstinence at weeks 5 through 8 was 30% for cytisinicline compared to 8% for placebo ($p= 0.005$). Adherence to study treatment was 98% in the 3.0 mg TID arm and cytisinicline was well-tolerated with no serious adverse events reported.

Investor Day and KOL Roundtable Discussion

The Company hosted its first investor day on September 20th, 2019, featuring an updated ORCA-1 data presentation and a roundtable discussion of smoking cessation medical experts, Dr. Mitchell Nides, Dr. Nancy Rigotti, Dr. Judith Prochaska, and Dr. Scott Leischow. The experts highlighted the critical need for the availability of new treatments, like cytisinicline, as an aid to smoking cessation. A replay of the event can be found at http://ir.achievelifesciences.com/events-and-webcasts.

Financial Results

As of September 30, 2019, the company's cash, cash equivalents, and restricted cash was $7.4 million. Total operating expenses for the three and nine months ended September 30, 2019 were $3.7 million and $13.3 million, respectively. Total net loss for the three and nine months ended September 30, 2019 was $3.7 million and $13.2 million, respectively.

As of November 6, 2019 Achieve had 8,352,764 shares outstanding.

Conference Call Details

Achieve will host a conference call at 8:00 a.m. Eastern time today, Wednesday, November 6, 2019To 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 7196429. 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 more than eight 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.

[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017

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

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.

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, expectations from current data, expectations regarding when trial data may be reported, 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.

Achieve Contact

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	1,824	1,541	7,911	3,787
General and administrative	1,893	1,753	5,408	5,317
Total operating expenses	3,717	3,294	13,319	9,104
Loss from operations	(3,717)	(3,294)	(13,319)	(9,104)
Other income (expense)	44	54	118	54
Net loss	$ (3,673)	$ (3,240)	$ (13,201)	$ (9,050)
Basic and diluted net loss per share	$ (0.45)	$ (0.71)	$ (1.80)	$ (3.70)
Weighted average number of basic and diluted common shares	8,100,249	4,533,943	7,342,087	2,448,962

Consolidated Balance Sheets
(In thousands)

	September 30, 2019	December 31, 2018
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 7,425	$ 14,654
Prepaid expenses and other current assets	264	933
Property, equipment and other assets	254	153
Right-of-use assets	372	—
License agreement	2,143	2,310
Goodwill	1,034	1,034
Total assets	$ 11,492	$ 19,084
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,941	$ 3,259
Current portion of long-term obligations	198	11
Long-term obligations	212	12
Stockholders' equity	8,141	15,802
Total liabilities and stockholders' equity	$ 11,492	$ 19,084