
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 8, 2019

ACHIEVE LIFE SCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

033-80623
(Commission File Number)

95-4343413
(IRS Employer
Identification No.)

1040 West Georgia Street, Suite 1030, Vancouver,
B.C. V6E 4H1
(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 (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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
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 August 8, 2019, Achieve Life Sciences, Inc. issued a press release announcing its financial results for the second quarter ended June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release of Achieve Life Sciences, Inc. dated August 8, 2019</u>

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: August 8, 2019

/s/ John Bencich

John Bencich
Chief Financial and Operating Officer

Achieve Reports Financial Results for Second Quarter 2019 and Provides Cytisinicline Clinical Development Update

SEATTLE, Wash and VANCOUVER, British Columbia, August 8, 2019-- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today provided an update on the cytisinicline clinical development program and announced second quarter 2019 financial results.

Q2 2019 Highlights

- Reported positive results from the Phase 2b ORCA-1 dose-selection trial evaluating cytisinicline in 254 smokers. Cytisinicline demonstrated a statistically significant improvement in quit rates for a simplified 3.0 mg, three times daily dose. Cytisinicline was well-tolerated with no serious adverse events reported.
- Announced ORCA-1 data has been accepted for an oral presentation at the Society for Research on Nicotine & Tobacco Europe (SRNT-E) 19th Annual Conference to be held in Oslo, Sept. 12-14, 2019
- Patent granted in the U.S. for new cytisinicline succinate salt formulation designed to enhance product stability and long-term potency
- Received \$4.2 million in proceeds from exercise of warrants

"It has been an exciting quarter with the release of the positive ORCA-1 Phase 2b trial results that demonstrated impressive smoking cessation efficacy, safety, and cytisinicline treatment adherence," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. "The data exceeded our expectations and provide a clear path forward for our future Phase 3 program."

ORCA-1 Positive Study Results

The Phase 2b ORCA-1 trial of cytisinicline in 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.

Cytisinicline Data Accepted for Presentation

Data from the Phase 2b ORCA-1 trial has been accepted for oral presentation at the SRNT-E Annual Conference, to be held in Oslo, September 12-14, 2019. The abstract "*A Multicenter, Double-blind, Randomized, Placebo-controlled Phase 2b Trial of Cytisinicline in Adult Smokers*" and two, oral presentations will include updated cytisinicline data from the recently completed trial.

Patent Granted in the U.S. for Novel Formulation of Cytisinicline

The U.S. Patent and Trademark Office has granted Achieve a patent on succinate salt of cytisinicline and use thereof. The patent covers a novel salt form of cytisinicline, namely cytisinicline succinate, and pharmaceutical compositions and dosage forms. Achieve has been pursuing cytisinicline



succinate salt as a novel new drug product formulation that may further enhance cytisinicline product stability and long-term potency.

Received \$4.2 Million from Exercise of Warrants

Achieve announced that it had entered into an agreement with a single investor to exercise outstanding warrants that provided an aggregate of \$4.2 million in total proceeds. In exchange for the warrant exercise, Achieve issued to the investor a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of Common Stock at an exercise price of \$4.50 per share. The Company filed an S-1 registration statement on July 24, 2019 covering the resale of the shares issuable upon exercise of the new warrant.

Financial Results

As of June 30, 2019, the company's cash, cash equivalents, and restricted cash was \$10.5 million. Total operating expenses for the three and six months ended June 30, 2019 were \$3.7 million and \$9.6 million, respectively. Total net loss for the three and six months ended June 30, 2019 was \$3.6 million and \$9.5 million, respectively.

As of August 8, 2019 Achieve had 8,097,763 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 p.m. Eastern time today, Thursday, August 8, 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 6587726. 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 nearly seven million deaths annually worldwide. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking². 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.

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

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



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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"ORCA is a trademark of Achieve Life Sciences, Inc."



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

	Three months ended June 30,		Three months ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	2,032	1,045	6,087	2,246
General and administrative	1,630	1,751	3,515	3,564
Total operating expenses	3,662	2,796	9,602	5,810
Loss from operations	(3,662)	(2,796)	(9,602)	(5,810)
Other income (expense)	38	8	74	-
Net loss before income taxes	\$ (3,624)	\$ (2,788)	\$ (9,528)	\$ (5,810)
Recovery of deferred income taxes	-	-	-	-
Net loss	\$ (3,624)	\$ (2,788)	\$ (9,528)	\$ (5,810)
Basic and diluted net loss per share	\$ (0.50)	\$ (1.82)	\$ (1.37)	\$ (4.18)
Weighted average number of basic and diluted common shares	7,189,672	1,529,532	6,956,722	1,389,209

Consolidated Balance Sheets
(In thousands)

	June 30, 2019	December 31, 2018
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 10,496	\$ 14,654
Prepaid expenses and other current assets	356	933
Property, equipment and other assets	256	153
Operating lease right-of-use assets	414	-
License agreement	2,199	2,310
Goodwill	1,034	1,034
Total assets	\$ 14,755	\$ 19,084
Liabilities and stockholders' equity:		
Warrant Liability		-
Current portion of long-term obligations	16	11
Current portion of long-term lease liability	176	-
Long-term obligations	20	12
Long-term lease liability	243	-
Stockholders' equity	11,504	15,802
Total liabilities and stockholders' equity	\$ 14,755	\$ 19,084