
**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 6, 2020

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, 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 (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))

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 6, 2020, Achieve Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2020. 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 6, 2020.</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 6, 2020

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

Achieve Reports Financial Results for Second Quarter 2020 and Provides Update on Cytisinicline Development Program

SEATTLE, Wash and VANCOUVER, British Columbia, August 6, 2020– 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 announced second quarter 2020 financial results and provided an update on the cytisinicline clinical development program.

Recent Highlights

- Announced successful topline results from the investigator initiated RAUORA head-to-head non-inferiority clinical trial comparing cytisinicline and Chantix® (varenicline) as a treatment to quit smoking
- Closed a Registered Direct Offering for gross proceeds of approximately \$6 million, prior to deducting placement agent commissions and estimated offering expenses
- Entered into an Underwritten Public Offering for estimated gross proceeds of \$7.5 million, prior to deducting underwriting discounts and commissions and estimated offering expenses. This financing is expected to close on or about August 6, 2020, subject to the satisfaction of customary closing conditions
- New patent granted in the U.S. for novel analogs of cytisinicline for use in CNS and addiction indications

“It has been a busy and exciting quarter with new evidence further reinforcing our belief that cytisinicline has the potential to provide a more tolerable cessation treatment to millions of smokers who want to quit,” commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. We continue to focus our efforts on initiation of the 750 patient Phase 3 ORCA-2 trial in the second-half of 2020, subject to the ability to conduct the trial safely in light of the COVID-19 pandemic.”

Successful RAUORA Head-to-Head vs Chantix® Study Results

Achieve announced the successful topline results from the New Zealand RAUORA Phase 3 non-inferiority clinical trial comparing cytisinicline to varenicline (Chantix) in Māori (indigenous New Zealanders) and whānau (family) of Māori. The trial achieved statistical significance in showing that cytisinicline plus behavioral support was at least as effective as varenicline plus behavioral support at six months. In addition, the trial showed that cytisinicline resulted in significantly fewer reported adverse events when compared to varenicline. The study was led by Dr. Natalie Walker, Associate Professor at the University of Auckland, and was funded by the Health Research Council of New Zealand. The final RAUORA trial results have been submitted for presentation at The Society for Research on Nicotine and Tobacco Europe (SRNT-E) Annual Meeting in September 2020.



Closed Registered Direct Offering for Gross Proceeds of \$6 million

Achieve entered into a securities purchase agreement with certain institutional investors providing for the purchase and sale of 731,707 shares of common stock at a price of \$8.20 per share in a registered direct offering, resulting in total gross proceeds of approximately \$6 million, prior to deducting placement agent fees and estimated offering expenses. The financing was closed in early July 2020.

Entered into an Underwritten Public Offering for Gross Proceeds of \$7.5 million

On August 3, 2020, Achieve entered into an Underwritten Public Offering to which it will sell 569,043 shares of common stock, including 92,856 shares subject to the underwriters' option to purchase additional shares, at a price of \$10.50 per share, and 142,857 pre-funded warrants at a price of \$10.499 per pre-funded warrant, which represents the per share public offering price for the shares of common stock less \$0.001 per shares exercise price for each pre-funded warrant. Total gross proceeds from the offering are expected to be approximately \$7.5 million, prior to deducting underwriting discounts and commissions and estimated offering expenses. This financing is expected to close on or about August 6, 2020, subject to the satisfaction of customary closing conditions.

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

Achieve announced that the United States Patent and Trademark Office has granted Achieve a patent on derivatives of cytinicline and use thereof. The newly patented analogs provide the opportunity for selective targeting of nAChRs in the brain in order to treat a number of conditions, such as Alzheimer's disease, depression, anxiety, schizophrenia, epilepsy, Parkinson's disease and addiction.

Financial Results

As of June 30, 2020, the company's cash, cash equivalents, and restricted cash was \$12.2 million, exclusive of the funds from the July and August financings totaling \$13.5 million gross proceeds. Total operating expenses for the three and six months ended June 30, 2020 were \$2.9 million and \$6.3 million, respectively. Total net loss for the three and six months ended June 30, 2020 was \$2.9 million and \$6.2 million, respectively.

As of August 6, 2020, Achieve had 3,587,205 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30pm Eastern time today, Thursday, August 6, 2020. 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 1661409. 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 worldwide¹. 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 and nicotine addiction 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 ability to secure any non-dilutive financing, the timing and nature of cytisinicline clinical development activities, the potential market size for cytisinicline, the potential benefits of cytisinicline, the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, and the development and effectiveness of new treatments. 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; risks related to the impact on our business of the COVID-19 pandemic or similar public health crises 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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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



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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	2020	2019	2020	2019
Operating expenses:				
Research and development	1,103	2,032	2,644	6,087
General and administrative	<u>1,815</u>	<u>1,630</u>	<u>3,631</u>	<u>3,515</u>
Total operating expenses	<u>2,918</u>	<u>3,662</u>	<u>6,275</u>	<u>9,602</u>
Loss from operations	(2,918)	(3,662)	(6,275)	(9,602)
Other income (expense)	(4)	38	33	74
Net loss	<u>\$ (2,922)</u>	<u>\$ (3,624)</u>	<u>\$ (6,242)</u>	<u>\$ (9,528)</u>
Basic and diluted net loss per share	<u>\$ (1.68)</u>	<u>\$ (10.08)</u>	<u>\$ (3.79)</u>	<u>\$ (27.39)</u>
Weighted average number of basic and diluted common shares	<u>1,744,014</u>	<u>359,484</u>	<u>1,645,426</u>	<u>347,836</u>

Consolidated Balance Sheets
(In thousands)

	<u>June 30,</u>	<u>December 31,</u>
	2020	2019
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 12,161	\$ 16,714
Prepaid expenses and other current assets	545	670
Property, equipment and other assets	502	244
Right-of-use assets	240	329
License agreement	1,976	2,087
Goodwill	<u>1,034</u>	<u>1,034</u>
Total assets	<u>\$ 16,458</u>	<u>\$ 21,078</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 1,645	\$ 2,666
Current portion of long-term obligations	165	203
Long-term obligations	110	159
Stockholders' equity	<u>14,538</u>	<u>18,050</u>
Total liabilities and stockholders' equity	<u>\$ 16,458</u>	<u>\$ 21,078</u>