

August 6, 2020



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

SEATTLE and VANCOUVER, British Columbia, Aug. 6, 2020 /CNW/ -- 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 cytisinicline 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 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 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.

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Chantix® is a registered trademark of Pfizer Inc.

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

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	1,103	2,032	2,644	6,087
General and administrative	1,815	1,630	3,631	3,515

Total operating expenses	2,918	3,662	6,275	9,602
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)

	June 30, 2020	December 31, 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	1,034	1,034
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	14,538	18,050
Total liabilities and stockholders' equity	<u>\$ 16,458</u>	<u>\$ 21,078</u>

[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

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