November 9, 2017

# Achieve Reports Financial Results for Third Quarter 2017

BOTHELL, Wash. and VANCOUVER, British Columbia, Nov. 9, 2017 /PRNewswire/ -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, today announced financial results for the third quarter ended September 30, 2017.


**Third Quarter 2017 Highlights**

- Consummated merger with OncoGenex Pharmaceuticals

- Investigational New Drug (IND) application accepted by the U.S. Food and Drug Administration (FDA) enabling the commencement of cytisine development in the U.S.
- Initiated cytisine's clinical development activities in preparation for pivotal U.S. Phase 3 program
    - Commenced multi-dose study to evaluate the pharmacokinetic/pharmacodynamic characteristics of cytisine in smokers
    - Completed enrollment in a study evaluating the effect of food on the bioavailability of cytisine
- Entered into a share purchase agreement with Lincoln Park Capital Fund, LLC

"I'm extremely pleased with our progress during the period across both clinical and corporate development fronts. Clearly, joining the NASDAQ Capital Markets platform via our merger with OncoGenex was a major milestone as we advance cytisine, our smoking cessation treatment, toward its pivotal U.S. Phase 3 program which remains on track to initiate in mid-2018," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve.

On August 1, 2017, Achieve announced the closing of its merger with publicly listed OncoGenex Pharmaceuticals. The prevailing entity combined operations and employees from both companies with shareholders of Achieve becoming the majority stockholders of OncoGenex in a 1-for-11 reverse stock split with the trading symbol transitioning from OGXI to ACHV.

On August 10th, the U.S. Food and Drug Administration (FDA) accepted Achieve's Investigational New Drug (IND) application for cytisine which provided the Company authorization to commence clinical development of the smoking cessation treatment in the U.S. Cytisine has been approved and marketed in Central and Eastern Europe for more than 25 years. It is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,100 patients in Phase 3 clinical trials conducted in Europe and New Zealand. Achieve has also collaborated with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH), which has sponsored and completed a number of the preclinical IND-enabling studies .

In preparation for initiating cytisine's pivotal Phase 3 program in the U.S., the Company announced on August 16th, its Clinical Development Plan which entails two phase 1/2 studies aimed at assisting the design and implementation of the subsequent Phase 3 program. The first study was the evaluation of the effect of food on the bioavailability of cytisine, which has completed and data analysis is expected in Q4 2017. The second study was the evaluation of repeat-dose pharmacokinetic and pharmacodynamic characteristics of cytisine in smokers, which commenced in Q4 2017. Data from this repeat-dose study is expected in the first quarter of 2018.

On September 14, the Company announced that it had entered into a share purchase agreement with Lincoln Park Capital Fund, LLC in which Achieve may sell up to $11.0 million of shares of common stock over a 30 month term subject to certain limitations and conditions set forth in the purchase agreement. Through September 30, 2017, the company offered and sold 408,947 shares of common stock to Lincoln Park resulting in proceeds of $1.2 million net of offering costs. As consideration for entering into the Purchase Agreement, we issued to LPC 123,516 shares of common stock; no cash proceeds were received from the issuance of these shares. Achieve plans to utilize the net proceeds from this offering to advance its product candidate cytisine as well as for general corporate purposes. From

October 1, 2017 through November 9, 2017, we offered and sold 464,831 shares of our common stock pursuant to our Purchase Agreement with LPC. These sales resulted in gross proceeds to us of approximately $0.9 million.

**Financial Results**

As of September 30, 2017, the company's cash and cash equivalents were $8.0 million compared with $15,000 as of December 31, 2016.

Total operating expenses for the three and nine months ended September 30, 2017 were $2.4 million and $2.9 million, respectively, compared to $0.4 million and $1.1 million for the three and nine months ended September 30, 2016, respectively.

Net loss for the three and nine months ended September 30, 2017 was $6.5 million and $6.8 million, respectively, compared to $0.3 million and $0.7 million for the three and nine months ended September 30, 2016, respectively.

As of November 9, 2017 Achieve had 11,947,676 shares outstanding.

**About Achieve & Cytisine**

Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisine. Tobacco use is currently the leading cause of preventable death and is responsible for nearly six million deaths annually worldwide[1]. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking[2].

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. Two prior, large-scale Phase 3 clinical studies of cytisine, with favorable outcomes, have been successfully completed in over 2,000 patients. The TASC trial was a 740 patient, double-blind, placebo controlled trial conceived by Professor Robert West at University College London and funded by the U.K. National Prevention Research Initiative. The CASCAID trial was a 1,310 patient, single-blind, non-inferiority trial comparing cytisine to nicotine replacement therapy (NRT). The CASCAID trial was conceived by Dr. Natalie Walker, National Institute for Health Innovation, University of Auckland and funded by the Health Research Council of New Zealand. Both trials were published in the New England Journal of Medicine.

**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 timing of clinical development of cytisine, the market size for cytisine and the potential benefits of cytisine. 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 cytisine 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 cytisine; the risk that cytisine 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 the final Proxy Statement/Prospectus/Information Statement filed pursuant to Rule 424(b)(3) in connection with Achieve's recent merger, and 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 law.

**Achieve Contact**
Jason Wong
jwong@bplifescience.com
(415) 375-3340 ext. 4

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

| | Three months ended September 30, | | Twelve months ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Operating expenses: | | | | |
| Research and development | 825 | 69 | 948 | 206 |
| General and administrative | 1,550 | 329 | 1,902 | 899 |
| Total operating expenses | 2,375 | 398 | 2,850 | 1,105 |
| Loss from operations | (2,375) | (398) | (2,850) | (1,105) |
| Other income (expense) | (7,025) | (7) | (7,044) | (20) |
| Net loss before income taxes | $ (9,400) | $ (405) | $ (9,894) | $ (1,125) |
| Recovery of deferred income taxes | 2,927 | 137 | 3,051 | 377 |
| Net loss | $ (6,473) | $ (268) | $ (6,843) | $ (748) |
| Basic and diluted net loss per share | $ (0.90) | $ (12.62) | $ (2.81) | $ (35.23) |
| Weighted average number of basic and diluted common shares | 7,225,826 | 21,230 | 2,435,095 | 21,230 |

**Consolidated Balance Sheets**
**(In thousands)**

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Assets: | | |
| Cash, cash equivalents, short term investments and restricted cash | $ 8,293 | $ 15 |
| Amounts receivable | 70 | — |
| Prepaid expenses and other current assets | 535 | 3 |
| Property, equipment and other assets | 509 | — |
| License agreement | 2,588 | 2,755 |

| | | |
|---|---|---|
| Goodwill | 1,034 | 1,034 |
| Total assets | $ 13,029 | $ 3,807 |
| | | |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued liabilities | $ 2,297 | $ 2,244 |
| Stockholder loans with related parties | — | 829 |
| Current portion of long-term obligations | 31 | — |
| Warrant liability | 3 | — |
| Long term liabilities | 16 | — |
| Deferred tax liability | — | 124 |
| Stockholders' equity | 10,682 | 610 |
| Total liabilities and stockholders' equity | $ 13,029 | $ 3,807 |

[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011, Geneva: World Health Organization, 2011.

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

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