Filed Pursuant to Rule 424(b)(4)
Registration No. 333-234530

9,577,504 Class A Units consisting of common stock and warrants and
6,256 Class B Units consisting of shares of Series B Preferred Stock and warrants
(and 30,422,496 shares of common stock underlying shares of Series B Preferred Stock and warrants)

We are offering 9,577,504 Class A Units, with each Class A Unit consisting of one share of common stock, par value $0.001 per share (the "common stock"), and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the "Class A Units") at a public offering price of $0.60 per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of common stock at an exercise price per share of $0.60, subject to adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect, provided, however, in no event will the exercise price per share of the warrants be reduced to an amount less than $0.06 per share of common stock.

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, if they so choose, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%), Class B Units. Each Class B Unit consists of one share of Series B Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock"), convertible into 1,666 shares of common stock and warrants to purchase 1,666 shares of our common stock (together with the shares of common stock underlying such shares of Series B Preferred Stock and such warrants, the "Class B Units" and, together with the Class A Units, the "units") at a public offering price of $999.60 per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase 1,666 shares of common stock at an exercise price per share of $0.60, subject to adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect, provided, however, in no event will the exercise price per share of the warrants be reduced to an amount less than $0.06 per share of common stock.

The Class A Units and Class B Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of common stock, Series B Preferred Stock and warrants comprising such units are immediately separable and will be issued separately in this offering.

The underwriters have the option to purchase up to 3,000,000 additional shares of common stock and/or warrants to purchase up to 3,000,000 shares of common stock solely to cover overallotments, if any, at the price to the public less the underwriting discounts and commissions. The overallotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriters, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series B Preferred Stock) and warrants sold in the primary offering. The overallotment option is exercisable for 45 days from the date of this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol "ACHV". The closing price of our common stock on December 16, 2019, as reported by The Nasdaq Capital Market, was $0.77 per share. We do not intend to apply for listing of the warrants offered hereby or the shares of Series B Preferred Stock on any securities exchange or trading system.

Investing in our securities involves a high degree of risk. Before making any investment in these securities, you should consider carefully the risks and uncertainties in the section entitled "Risk Factors" beginning on page 15 of this prospectus.

	Per Class A Unit	Per Class B Unit	Total
Public offering price(1)	$ 0.60	$ 999.60	$12,000,000
Underwriting discount(2)(3)	$ 0.05	$ 49.97	$ 930,000
Proceeds, before expenses, to Achieve Life Sciences, Inc.	$ 0.55	$ 949.63	$11,070,000

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units, (i) a public offering price per share of common stock of $0.59 and (ii) a public offering price per warrant of $0.01, and (y) in respect of the Class B Units, (i) a public offering price per share of Series B Preferred Stock of $982.94 and (ii) a public offering price per warrant of $16.66.
(2) We have also agreed to reimburse the underwriters for certain expenses. See "Underwriting."
(3) We have granted a 45-day day option to the underwriters to purchase up to 3,000,000 additional shares of common stock and/or warrants to purchase up to 3,000,000 shares of common stock (up to 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series B Preferred Stock) and warrants sold in the primary offering) solely to cover overallotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

Ladenburg Thalmann
The date of this prospectus is December 17, 2019

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We have not, and the underwriters and their affiliates have not, authorized anyone to provide you with any information or to make any representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. We do not, and the underwriters and their affiliates do not, take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide to you. This prospectus is not an offer to sell or an offer to buy units in any jurisdiction where offers and sales are not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or any sale of units. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find More Information” in the prospectus.

Neither we nor the underwriters have done anything that would permit a public offering of the units or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the units and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere in this prospectus. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including the risk factors and the financial statements and related notes included in this prospectus. Unless the context requires otherwise, in this prospectus the terms "Achieve," the "Company," "we," "us" and "our" refer to Achieve Life Sciences, Inc., together with its subsidiaries, taken as a whole. This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

Company Overview

We are a clinical-stage pharmaceutical company committed to the global (excluding Central & Eastern Europe plus other territories) development and commercialization of cytisinicline for smoking cessation and nicotine addiction. The United States Adopted Names Council adopted cytisinicline as the nonproprietary, or generic, name for the substance also known as cytisine during the third quarter of 2018. Our primary focus is to address the global smoking and nicotine addiction epidemic, which is a leading cause of preventable death and is responsible for more than eight million deaths annually worldwide. We may expand our focus to address other methods of nicotine addiction such as e-cigarettes/vaping.

Cytisinicline is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by Sopharma AD for over 20 years under the brand name Tabex™. It is estimated that over 20 million people have used cytisinicline to help treat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand. Both trials were published in the New England Journal of Medicine in September 2011 and December 2014, respectively.

Cytisinicline is a naturally occurring, plant-based alkaloid from the seeds of the Laburnum anagyroides plant. Cytisinicline is structurally similar to nicotine and has a well-defined, dual-acting mechanism of action that is both agonistic and antagonistic. It is believed to aid in smoking cessation and the treatment of nicotine addiction by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms through agonistic binding to nicotine receptors and by reducing the reward and satisfaction associated with nicotine through antagonistic properties.

Overview of the Tobacco Epidemic

The World Health Organization, or WHO, estimates that there are approximately 1.1 billion smokers globally and that tobacco kills more than 8 million people each year. More than 7 million of those deaths are the result of direct tobacco use, while around 1.2 million are the result of the exposure of non-smokers to second-hand smoke.

Cigarette smoking is responsible for more than 480,000 deaths per year in the United States, including more than 41,000 deaths resulting from exposure to second-hand smoke, which equates to about one in five deaths annually, or 1,300 deaths every day. According to the American Cancer Society, smoking is a direct cause of approximately 80% of lung cancer deaths and is linked to 30% of all cancer deaths in the United States. Smoking remains the single largest preventable cause of death worldwide and in the United States.

The CDC estimates that the annual cost of smoking related illnesses in the United States is more than $300 billion annually in direct medical care and lost productivity. Over 16 million people in the United States are living with a disease caused by smoking. Among these diseases are cancer, heart disease, stroke, lung diseases, diabetes and chronic obstructive pulmonary disease, or COPD, which includes emphysema and chronic

bronchitis. Smoking also increases risk for tuberculosis, certain eye diseases and problems of the immune system, including rheumatoid arthritis.

Tobacco smoking is highly addictive and research suggests that nicotine may be as addictive as heroin, cocaine and alcohol. The CDC estimates that more people in the United States are addicted to nicotine than any other drug and reports that, in 2015, nearly 70% of smokers desired to quit and 55% made an attempt to do so in the prior year. Despite the high number of attempts, fewer than one in ten people are successful in their attempt to quit each year. Additionally, up to 60% of people who quit smoking relapse in the first year.

One increasingly popular alternative to smoking is the use of e-cigarettes, or vaping, which deliver liquid nicotine into a mist or vapor which is inhaled. This method of consumption avoids the chemicals that are associated with cigarette smoke, but may have other associated health and safety issues. The emerging use of e-cigarettes is contributing to the growing population of people who are addicted to nicotine.

According to the Annals of Internal Medicine, data reported in 2018 estimated approximately 10.8 million American adults usee-cigarettes and half of these users are under the age of 35. The United States Food and Drug Administration, or FDA, considers e-cigarette use an epidemic, particularly in youth. From 2017 to 2018, vaping increased by 78% among high school students (11.7% to 20.8%) and by 48% among middle school students (3.3% to 4.9%). Not only does e-cigarette use come with risks of its own, but research has also shown that youth who vape are more likely to start smoking combustible cigarettes.

The Global Smoking Cessation Market

Coherent Market Insights Report “Smoking Cessation and Nicotine De-addiction Products Market, 2016-2017” estimated that global revenues for smoking cessation and nicotine de-addiction products in 2016 was approximately $12.8 billion, including nicotine replacement therapies, or NRT, e-cigarettes and drug therapy. In 2017, in the United States alone, sales for NRT and drug therapy were estimated to be $3.8 billion and are expected to grow to $5.7 billion by 2024.

Two prescription oral treatments for smoking cessation are currently available in the United States: Chantix® (varenicline), marketed by Pfizer, and Zyban® (bupropion), marketed by GlaxoSmithKline (as well as generic manufacturers). Chantix requires a three-month treatment period and Zyban is recommended for between 7 and 12 weeks. Both of these prescription treatments have been proven effective in aiding smoking cessation; however, both are also associated with significant side effects and drop offs from treatment. Chantix’s labeling indicates elevated instances of nausea, abnormal dreams, constipation, flatulence and vomiting may be experienced by Chantix-treated patients compared to placebo-treated patients, and Zyban’s labeling discloses potential adverse reactions including insomnia, rhinitis, dry mouth, dizziness, nervous disturbance, anxiety, nausea, constipation, arthralgia and seizures. High uptake into the brain combined with activity at “off target” receptors could be responsible for Chantix’s adverse event profile.

Global sales of Chantix® exceeded $1 billion in 2018. Of those sales, $838 million, approximately 77%, were attributable to the U.S. market.

The vast majority of Over-the-Counter, or OTC, smoking cessation aids are NRTs. NRTs come in many forms, including gums, lozenges and patches, have been shown to be less effective than prescription drugs. For example, a Cochrane Group independent database review of nicotine receptor partial agonists published in 2016 compared varenicline (Chantix) with a number of NRTs and varenicline has been proven to be more effective than the NRTs, as demonstrated in head-to-head studies.

Our Product Candidate

Our product candidate, cytisinicline, is a naturally occurring, plant-based alkaloid from the seeds of the Laburnum anagyroides plant. Cytisinicline is structurally similar to nicotine and has a well-defined, dual-acting

mechanism of action that is both agonistic and antagonistic. It is believed to aid in smoking cessation, or nicotine addiction, by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms through agonistic binding to nicotine receptors and by reducing the reward and satisfaction associated with nicotine through antagonistic properties.

Cytisinicline is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by Sopharma AD for over 20 years under the brand name Tabex™. It is estimated that over 20 million people have used cytisinicline to help treat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand. Both trials were published in the New England Journal of Medicine in September 2011 and December 2014, respectively.

Cytisinicline Mechanism of Action

Cytisinicline is a partial agonist that binds with high affinity to thealpha-4 beta-2, or α4ß2, nicotinic acetylcholine receptors in the brain. Through dual-acting partial agonist/partial antagonist activity, cytisinicline is believed to help reduce nicotine cravings, withdrawal symptoms and reward and satisfaction associated with smoking. The α4ß2 nicotinic receptor is a well-understood target in addiction. When nicotine binds to this receptor, it causes dopamine to be released in the mid-brain, reinforcing the dopamine reward system. This receptor has been implicated in the development and maintenance of nicotine addiction. Cytisinicline is believed to act as a partial agonist at the α4ß2 nicotinic receptor, preventing nicotine from binding and releasing dopamine.

Cytisinicline Opportunity

We have an exclusive license and supply agreement with Sopharma for the development and commercialization of cytisinicline outside of Sopharma's territory, which consists of certain countries in Central and Eastern Europe, Scandinavia, North Africa, the Middle East and Central Asia, as well as Vietnam. We intend to develop and commercialize cytisinicline in the United States, and thereafter to target other markets outside of Sopharma's territory, such as Western Europe, Japan, Australasia, Southeast Asia and Latin and South America.

We are developing cytisinicline as an aid to smoking cessation and nicotine addiction to address the limitations of both prescription drugs and OTC products. We believe that a substantial market exists in the United States, European Union, or EU, and the rest of the world for a safe and effective smoking cessation treatment. Increasingly constrained healthcare budgets have focused government attention on drug pricing, which we believe cytisinicline can address by serving as a cost-effective alternative to existing treatments, with the potential for better efficacy than NRTs, and a potentially superior side effect profile than existing prescription smoking cessation products. Our goal is to obtain approval from the FDA and from other regulatory agencies for the sale and distribution of cytisinicline in the U.S. and subsequently to other countries outside of Sopharma's territory.

Non-clinical toxicology studies were sponsored by the National Center for Complementary and Integrative Health, or NCCIH, a division of the NIH and by the National Cancer Institute, or NCI, to assist in our Investigational New Drug Application, or IND. In June 2017, we filed our IND application for cytisinicline with the FDA, which included the NCCIH sponsored non-clinical studies. Additional non-clinical reproductive toxicology studies are also being conducted by NCCIH and NCI, with two such studies already submitted to the IND and a third study to be submitted upon completion. Other non-clinical toxicology studies that will be required for a New Drug Application, or NDA, include two longer-term chronic toxicology studies and two carcinogenicity studies, which are in distinct stages of execution as Achieve Sponsored studies. One of the chronic toxicology studies has been completed and submitted to FDA, while the second chronic toxicology study is in progress and is expected to be completed in 2020. Additionally, one of the carcinogenicity studies is currently in progress, while the second carcinogenicity study is planned for initiation during Phase 3 development.

In August 2017, we initiated the Phase 1 clinical study evaluating the effect of food on the bioavailability of cytisinicline in normal healthy volunteers. We completed the food effect study and announced the results in November of 2017 demonstrating similar bioavailability of cytisinicline in fed and fasted subjects.

In October 2017, we initiated a clinical study assessing the repeat-dose pharmacokinetics, or PK, and pharmacodynamics, or PD, effects of 1.5 mg and 3.0 mg cytisinicline in 36 healthy volunteer smokers when administered over the standard 25-day course of treatment as marketed by Sopharma in their territories. Of the 36 subjects, 24 were to be 18-65 years of age and 12 were to be greater than 65 years of age. Final results were presented at the Annual Meeting of the Society for Research on Nicotine and Tobacco, or SRNT, in February 2019. The study randomized a total of 26 subjects, which included only 2 of the intended 12 subjects of an age greater than 65, due to difficulty enrolling within this age group. All 26 subjects completed the study. Predictable increases in plasma cytisinicline concentrations were observed with increasing unit dosing from 1.5 mg to 3.0 mg. Smokers in the study were not required to have a designated or predetermined quit date. Overall, subjects had an 80% reduction in cigarettes smoked, 82% reduction in expired carbon monoxide, and 46% of the subjects achieved biochemically verified smoking abstinence by day 26. Subjects who received 3.0 mg cytisinicline over the 25 days had a trend for higher smoking abstinence compared to subjects who received 1.5 mg cytisinicline. The adverse events, or AEs, observed were mostly mild with transient headaches as the most commonly reported event. No severe or serious AEs were observed in the study.

In December 2017, we initiated a series of drug metabolism, drug-to-drug interaction, and transporter studies of cytisinicline and results from these studies were announced in June 2018. These studies demonstrated that cytisinicline has no clinically significant interaction with any of the hepatic enzymes commonly responsible for drug metabolism nor clinically significant interaction with drug transporters. This suggests that cytisinicline may be administered with other medications without the need to modify the dose of any co-administered medications. We will continue to evaluate any new FDA guidance on whether additional drug-to-drug interactions studies will be required prior to a future NDA filing.

We have met with the FDA and with other national regulatory authorities in Europe to identify the steps required for the approval of cytisinicline. We held an end of Phase 2 meeting with the FDA in May 2018 to review and receive guidance on our Phase 3 clinical program and overall development plans for cytisinicline to support an NDA. This review included submitted results from non-clinical studies, standard drug-to-drug interaction and reproductive/teratogenicity studies. Detailed plans for chronic toxicology, carcinogenicity studies, and additional clinical studies regarding renal impairment, QT interval prolongation, longer term exposure and adequate demonstration of safety and efficacy from our planned randomized, placebo-controlled, Phase 3 clinical trials were also discussed.

In 2018, Sopharma commercially launched a newly formulated cytisinicline tablet with improved shelf life in their territories. In May 2018, we initiated a study to evaluate the effect of food on the bioavailability of cytisinicline in volunteer smokers using this new formulation and data results were announced in September 2018. The study demonstrated similar bioavailability of cytisinicline in fed and fasted subjects. Cytisinicline was extensively absorbed after oral administration with maximum cytisinicline concentration levels observed in the blood within less than two hours with or without food. Total excretion levels of cytisinicline also remained equivalent in both the fed and fasted states, and the 3.0 mg dose using this new formulation of cytisinicline was well tolerated.

In December 2018, we announced that the FDA was in agreement with our Initial Pediatric Study Plan, specifically, providing a full waiver for evaluating cytisinicline in a pediatric population. The reasons for the full waiver were based on the low numbers of children smoking under the age of 12 and the logistical difficulties of recruiting treatment-seeking smokers in the adolescent age group. The agreed upon Initial Pediatric Study Plan is expected to be included as part of our future application for marketing approval of cytisinicline.

In March 2019, we initiated a clinical trial to assess the dose limiting AEs that would define the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. This study evaluated smokers who received one single dose of cytisinicline. The starting dosage of cytisinicline was 6.0 mg and was to be increased in separate groups of subjects for each escalated dose level until stopping criteria (based on the occurrence of dose-limiting AEs) were reached. A safety review after each dose level was performed by an independent Data Safety Monitor Committee, or DSMC, before escalation to the next dose level. Six dose levels were pre-planned with 21.0 mg cytisinicline as the highest dose level. When the MTD was not reached at 21.0 mg, the study was amended to evaluate doses up to 30.0 mg, as recommended by the DSMC. At this 30.0 mg dose, the stopping criteria of serious or severe AEs were still not met, but the DSMC recommended stopping the study since the frequency of gastrointestinal symptoms were approaching an MTD level. The results have been reviewed with the FDA and it has agreed that further escalation beyond the single 30.0 mg dose is not required. This Phase-1 study is a requirement for our future NDA and marketing approval of cytisinicline. It fulfills an FDA requirement to evaluate potential safety issues in the event patients exceed a recommended single dose outside of a clinical trial setting. These results do not impact the intended dosing planned for future Phase 3 cytisinicline clinical trials which was informed by the Phase 2b ORCA-1 trial discussed below.

In June 2019, we announced positive top line results for the Phase 2bORCA-1 trial and defined the dose selection of 3.0 mg, three times daily, or TID, for our Phase 3 development. ORCA-1 is the first in our ORCA (Ongoing Research of Cytisinicline for Addiction) Program that aims to evaluate the effectiveness of cytisinicline for smoking cessation, nicotine addiction therapy, and potential benefit in other indications.

ORCA-1 was initiated in October 2018 and evaluated 254 smokers in the United States. The trial evaluated both the 1.5 mg and 3.0 mg doses of cytisinicline on the standard declining titration schedule as well as a more simplified TID dosing schedule, both over 25 days. The trial was randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. Subjects were treated for 25 days, provided behavioral support, and followed up for an additional four weeks to assess smoking abstinence.

The primary endpoint in the study was the reduction in daily smoking, a self-reported measure. Three of the four cytisinicline treatment arms demonstrated a statistically significant reduction, $p<0.05$, compared to placebo. The fourth arm trended to significance ($p= 0.052$). Across all treatment arms, over the 25-day treatment period, subjects on cytisinicline experienced a 74-80% median reduction in the number of cigarettes smoked, compared to a 62% reduction in the placebo arms.

The secondary endpoint of the trial was a4-week continuous abstinence rate, which is the relevant endpoint for regulatory approval. All cytisinicline treatment arms showed significant improvements in abstinence rates compared to the placebo arms. The most impressive results were observed in the 3.0 mg TID cytisinicline arm which demonstrated a 54% abstinence rate starting at week 4, compared to 16% for placebo ($p<0.0001$) and a continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline compared to 8% for placebo ($p= 0.005$). At week 4, all four cytisinicline arms demonstrated statistically significant ($p<0.05$) reductions in expired carbon monoxide, or CO, a biochemical measure of smoking activity. Expired CO levels had declined by a median of 71-80% in the cytisinicline treatment arms, compared to only 38% in the placebo arms. The greater reductions in expired CO levels for the cytisinicline arms versus placebo suggest that placebo-treated subjects may have over-reported their reduction in cigarettes smoked or overcompensated with greater inhalation while smoking fewer cigarettes.

Cytisinicline was well-tolerated with no serious AEs reported. The most commonly reported (>5%) AEs across all cytisinicline treatment arms versus placebo arms were abnormal dreams, insomnia, upper respiratory tract infections, and nausea. In the 3.0 mg TID treatment arm versus placebo arms, the most common AEs were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%), respectively. Compliance with study treatment was greater than 94% across all arms.

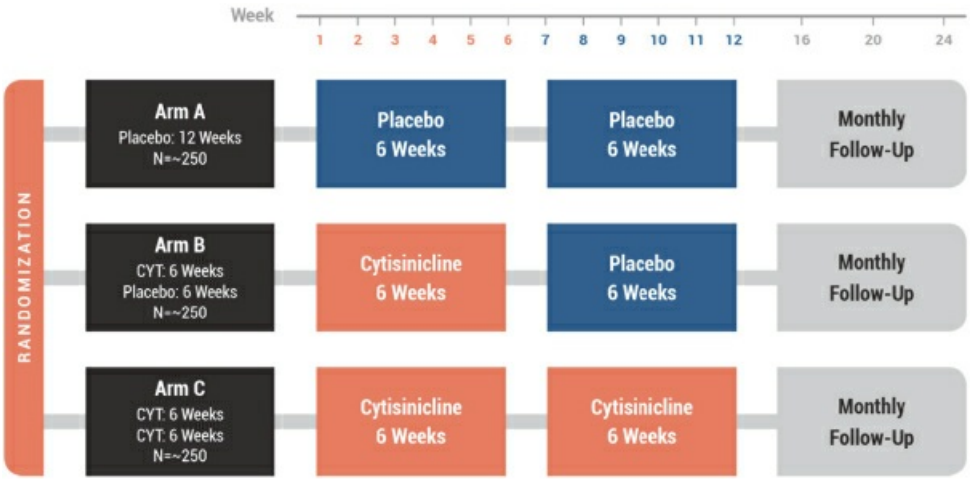
Based on the results of the ORCA-1 trial, we have selected 3.0 mg TID for Phase 3 development. Overall, the 3.0 mg dose administered TID demonstrated the best overall safety and efficacy when compared to other doses and administrations studied in ORCA-1.

We presented the ORCA-1 results in September 2019 at the annual European meeting of the Society for Research on Nicotine and Tobacco (SRNT) held in Oslo, Norway. We also plan to discuss the trial's outcome with the FDA and finalize Phase 3 protocol details in the fourth quarter 2019.

In November 2019, we held a type C meeting with the FDA to review theORCA-1 results and our revisions to the Phase 3 clinical program using the simplified 3.0 mg TID dosing schedule. The FDA agreed that the 3.0 mg TID dosing schedule is acceptable. We also discussed with the FDA timing for the submission of interim data from the second ongoing chronic toxicology study to support the longer treatment durations of 6- and 12-weeks in the Phase 3 clinical program. We anticipate the interim chronic toxicology data to be submitted during the first quarter of 2020 just prior to initiating the Phase 3 program.

We plan to initiate a Phase 3 trial in the first half of 2020 to evaluate the efficacy and safety of 3.0 mg TID of cytisinicline in smokers within the United States, subject to the availability of capital. The study plans to compare 3.0 mg TID of cytisinicline dosing versus placebo and will include behavioral support for all subjects. Co-primary endpoints of the study are an assessment of smoking abstinence during the last four weeks of6-week and 12-week treatment periods, compared to similar placebo treatment periods. Secondary endpoints include smoking abstinence out to 24 weeks.

The study schematic of the Phase 3 study is as follows:



Subject to the availability of capital, we are targeting the following milestones for the Phase 3 study:

Milestone	Estimated Timing
Phase 3 study initiation	1H 2020
Last patient enrolled in Phase 3	Mid 2020
Last patient last visit in Phase 3	2H 2020
Top line data results Phase 3	1H 2021

We are also considering potential clinical studies in users of e-cigarettes. This is an important area of focus given the youth vaping epidemic and the increasing number of vaping-related lung illnesses that have recently been reported. The number of e-cigarette users continues to grow and, according to data published in the Annals of Internal Medicine in 2018, there are a reported 10.8 million e-cigarette users in the United States alone. The National Institute on Drug Abuse, or NIDA, a division of the NIH, has tobacco/nicotine and vaping on their list of Drugs of Abuse. While e-cigarettes have been viewed as safer than combustible cigarettes, the long-term safety of e-cigarettes is still unproven and may lead to a substitute form of nicotine addiction. Given the mechanism of action of cytisinicline, we believe it could be used to help address nicotine addiction for e-cigarette users. We are currently exploring non-dilutive funding sources as a way to potentially move forward with clinical studies in this setting.

Cytisinicline Clinical Trials

Cytisinicline has been previously tested in two large, randomized, independent investigator-sponsored Phase 3 clinical trials conducted according to Good Clinical Practice, or GCP requirements of the FDA, in more than 2,000 participants. The objective by these independent groups was to further define the efficacy and safety of cytisinicline according to current clinical development standards. Subsequently, we ran the Phase 2b ORCA-1 dose selection trial in 254 smokers in the United States to evaluate the safety and efficacy of alternative cytisinicline dosing and schedules compared to respective placebo groups.

TASC Trial

The Tabex Smoking Cessation, or TASC, trial, was sponsored by the United Kingdom, or U.K., Centre for Tobacco Control Studies and evaluated cytisinicline versus placebo in 740 primarily moderate-to-heavy smokers treated for 25 days in a single center in Warsaw, Poland. The TASC trial was designed as a Real World Evidence trial of cytisinicline that included minimal behavioral support. The primary outcome measure was sustained, biochemically verified smoking abstinence for 12 months after the end of treatment. The TASC trial was conceived by Professor Robert West (Department of Epidemiology and Public Health, University College London) and was funded by a grant from the National Prevention Research Initiative, including contributions from Cancer Research U.K., the U.K. Medical Research Council, U.K. Department of Health and others. We, through our partner Sopharma, provided the study drug used in this trial.

The results of the TASC trial were published in the New England Journal of Medicine in September 2011. The rate of sustained 12-month abstinence was 8.4% in the cytisinicline arm as compared with 2.4% in the placebo group ($p=0.001$). These results showed that cytisinicline was 3.4 times more likely than a placebo to help participants stop smoking and remain non-smokers for one year. The rate of sustained 6-month abstinence was 10.0% in the cytisinicline arm as compared with 3.5% in the placebo group ($p<0.001$). Cytisinicline was well tolerated with a slight but significant increase in combined gastrointestinal AEs (upper abdominal pain, nausea, dyspepsia and dry mouth; cytisinicline 51/370 (13.8%) and placebo 30/370 (8.1%). Otherwise the safety profile of cytisinicline was similar to that of placebo with no other significant differences in the rate of side effects in the two trial arms.

A summary of AEs reported in 10 or more subjects in the TASC trial is included in the table below.

TASC — Adverse Events Reported by 10 or More Study Participants(1)

Event	Cytisine (N=370)	Placebo (N=370)
	percent (number)	
Any gastrointestinal event	13.8%(51)	8.1%(30)
Upper abdominal pain	3.8(14)	3.0(11)
Nausea	3.8(14)	2.7(10)
Dyspepsia	2.4(9)	1.1(4)
Dry mouth	2.2(8)	0.5(2)
Any psychiatric event	4.6%(17)	3.2%(12)
Dizziness	2.2(8)	1.1(4)
Somnolence	1.6(6)	1.1(4)
Any nervous system event	2.7%(10)	2.4%(9)
Headache	1.9(7)	2.2(8)
Skin and subcutaneous tissue	1.6%(6)	1.4%(5)

(1) The incidence of events was analyzed according to the *Medical Dictionary for Regulatory Activities* System Organ Class, or SOC, categorization and preferred terms. Participants who reported more than one event in a system category were counted only once for the category. SOC categories for other events (those reported by fewer than 10 participants) were as follows: general (five events within cytisine and five with placebo), cardiac (four with cytisine and two with placebo), musculoskeletal and connective tissue (three with cytisine and three with placebo), infections (one with placebo), immune system (one with placebo) and metabolism and nutrition (one with placebo).

CASCAID Trial

The second Phase 3 trial, the Cytisine As a Smoking Cessation Aid, or CASCAID,non-inferiority trial, was sponsored by the Health Research Council of New Zealand and was an open-label trial that randomized 1,310 adult daily heavy smokers. Patients were randomized to receive either cytisinicline for 25 days or NRT for 8 weeks. Both treatment groups were offered low intensity telephone behavioral support during trial treatment. The primary outcome measure was continuous self-reported abstinence from smoking one month after quit date. The CASCAID trial was conducted by the Health Research Council of New Zealand. We, through our partner Sopharma, provided the cytisinicline in form of commercial Tabex™ used in this trial.

The results of the CASCAID trial, which were published in the New England Journal of Medicine in December 2014, showed that cytisinicline was superior to NRT for smoking cessation and, specifically, that cytisinicline was 1.43 times more likely than nicotine gums or patches to help participants stop smoking and remain non-smokers for six months. The rate of continuous one-month abstinence was 40% in the cytisinicline arm as compared with 31% in the NRT arm ($p<0.001$). A secondary outcome included the rate of continuous six-month abstinence which was 22% in the cytisinicline arm as compared with 15% in the NRT arm ($p=0.002$). Cytisinicline was generally well tolerated, although self-reported AEs were slightly higher in the cytisinicline arm compared with the NRT arm. The most frequent AEs for cytisinicline were nausea and vomiting (30/665 (4.6%)) and sleep disorders (28/665 (4.2%)). Reports of these same AEs in the NRT arm were as follows: nausea and vomiting (2/655 (0.3%)) and sleep disorders (2/655 (0.3%)).

A summary of AEs reported in subjects in the CASCAID trial is included in the table below.

CASCAID — Summary of All-Cause Adverse Events

Event	Cytisine (N=655)	NRT (N=655)
	percent (number)	
Participants with any adverse event % (no.)	31%(204)	20%(134)
Adverse events — % (no.)		
Any	44%(288)	27%(174)
In those who complied with treatment[1]	25%(161)	17%(113)
In those who did not comply with treatment	19%(127)	9%(61)
Participants with serious adverse event — % (no.)	7%(45)	39%(6%)
Serious adverse events — % (no.)[2][3]	9%(56)	7%(45)
Deaths[4]	0.2%(1)	0.2%(1)
Life-threatening events	0	0.2%(1)[5]
Hospitalizations	3%(18)	3%(18)
Otherwise medically important events	6%(37)	4%(25)
Severity of all adverse events — % (no.)[4]		
Mild	21%(139)	12%(78)
Moderate	17%(111)	12%(77)
Severe	6%(38)	3%(19)
Most frequent adverse events — % (no.)[5]		
Nausea and vomiting	5%(30)	0.3%(2)
Sleep disorders	4%(28)	0.3%(2)

(1) In the cytisine group, compliance was defined as having taken 80% or more of the required number of tablets within 1 month after the quit date (i.e., 80 or more tablets). In the NRT group, compliance was defined as having used NRT at 1 week and 1 month after the quit date. It was assumed that participants with missing data were not compliant.

(2) A serious event was defined as death, a life-threatening event, an event requiring hospitalization, or otherwise medically important event (i.e., the event does not belong in any of the other categories but may jeopardize the patient and may require medical or surgical intervention to prevent the occurrence of one or more other serious events).

(3) The categories are mutually exclusive.

(4) The severity of events was not medically verified.

(5) The list of most frequent AEs excludes signs and symptoms of cold and influenza. AEs were categorized in accordance with the *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10), Australian Modification.

Phase 2b ORCA-1 Trial

We conducted ORCA-1, initiated in October 2018 and evaluated 254 smokers in the United States, or U.S. The trial evaluated both the 1.5 mg and 3.0 mg doses of cytisinicline on the standard declining titration schedule as well as a more simplified TID dosing schedule, both over 25 days. The trial was randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. All subjects were treated for 25 days, provided behavioral support, and followed up for an additional four weeks to assess smoking abstinence.

The primary endpoint in the study was the reduction in daily smoking, a self-reported measure. Three of the four cytisinicline treatment arms demonstrated a statistically significant improvement, p<0.05, compared to placebo. The fourth arm trended to significance (p=0.052). Across all treatment arms, over the 25-day treatment period, subjects on cytisinicline experienced a 74-80% median reduction in the number of cigarettes smoked, compared to a 62% reduction in the placebo arms.

The secondary endpoint of the trial was a4-week continuous abstinence rate, which is the relevant endpoint for regulatory approval. All cytisinicline treatment arms showed significant improvements in abstinence rates compared to the placebo arms. The most impressive results were observed in the 3.0 mg TID cytisinicline arm which demonstrated a 54% abstinence rate starting at week 4, compared to 16% for placebo (p<0.0001) and a continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline compared to 8% for placebo (p=0.005). At week 4, all four cytisinicline arms demonstrated statistically significant (p<0.05) reductions in expired carbon monoxide (CO), a biochemical measure of smoking activity. Expired CO levels had declined by a median of 71-80% in the cytisinicline treatment arms, compared to only 38% in the placebo arms. The greater reductions in expired CO levels for the cytisinicline arms versus placebo suggest that placebo-treated subjects may have over-reported their reduction in cigarettes smoked or overcompensated with greater inhalation while smoking fewer cigarettes.

Cytisinicline was well-tolerated with no serious AEs reported. The most commonly reported (>5%) AEs across all cytisinicline treatment arms versus placebo arms were abnormal dreams, insomnia, upper respiratory tract infections, and nausea. In the 3 mg TID treatment arm versus placebo arms, the most common AEs were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%), respectively. Compliance with study treatment was greater than 94% across all arms.

A summary of AEs reported in subjects in theORCA-1 trial is included in the table below.

	TID		Downward Titration		Pooled	
	1.5 mg (n=52)	3.0 mg (n=50)	1.5 mg (n=51)	3.0 mg (n=50)	Cytisinicline (n=203)	Placebo (n=51)
At least 1 AE	20(39%)	21(42%)	29(57%)	23(46%)	93(46%)	24(47%)
URTI	5(10%)	3(6%)	3(6%)	2(4%)	13(6%)	7(14%)
Abnormal dreams	4(8%)	3(6%)	4(8%)	7(14%)	18(9%)	1(2%)
Nausea	1(2%)	3(6%)	5(10%)	3(6%)	12(6%)	5(10%)
Insomnia	4(8%)	3(6%)	3(6%)	4(8%)	14(7%)	1(2%)
Headache	6(12%)	2(4%)	1(2%)	1(2%)	10(5%)	2(4%)
Fatigue	3(6%)	1(2%)	1(2%)	2(4%)	7(3%)	2(4%)
Constipation	1(2%)	3(6%)	0(0%)	0(0%)	4(2%)	1(2%)

The outcome of the ORCA-1 trial was the selection of 3.0 mg TID for Phase 3 development. Overall, the 3.0 mg dose administered TID demonstrated the best overall safety and efficacy when compared to other doses and administrations studies in ORCA-1.

Safety Reporting

As cytisinicline has been marketed in Central and Eastern Europe for over 20 years, substantial safety reporting by Sopharma exists for cytisinicline including over 15 million cases. The most recent periodic safety update report submitted to the European authorities by Sopharma in 2018 did not contain new safety signals with cytisinicline.

Summary of Risk Factors

Investing in our securities involves substantial risk, and our business is subject to numerous risks and uncertainties. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our securities. Some of these risks include:

- We have incurred losses since inception, have a limited operating history on which to assess our business and anticipate that we will continue to incur losses for the foreseeable future;
- Substantial doubt exists as to our ability to continue as a going concern, and our ability to continue as a going concern is uncertain and dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis;
- Cytisine is currently our sole product candidate and there is no guarantee that we will be able to successfully develop and commercialize cytisine;
- We are dependent upon a single company for the manufacture and supply of cytisine;
- Results of earlier clinical trials of cytisine are not necessarily predictive of future results, and any advances of cytisine into clinical trials may not have favorable results or receive regulatory approval;
- Cytisine may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any;
- We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us;
- Sopharma may breach its supply agreement with us and sell cytisine into our territories or permit third parties to export cytisine into our territories and negatively affect our commercialization efforts of our products in our territories;
- We may not be successful in obtaining or maintaining necessary rights to cytisine, product compounds and processes for our development pipeline through acquisitions and in-licenses; and
- Management will have broad discretion as to the use of proceeds from this offering and we may use the net proceeds in ways with which you may disagree.

Business Organization

We were incorporated in California in October 1991 and subsequently reorganized as a Delaware corporation in March 1995. Our principal executive offices are located at 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1, and our telephone number is (604) 210-2217.

In August 2017, our company, then named OncoGenex Pharmaceuticals, Inc., completed its merger, or the Arrangement, with Achieve, as contemplated by the Merger Agreement between the companies. We then changed our name to Achieve Life Sciences, Inc. As a result of the Arrangement, Achieve became our wholly owned subsidiary. Achieve was formed in 2015 as a Delaware corporation. Extab Corporation, a Delaware corporation, which was formed in 2009, is also our wholly-owned subsidiary. Achieve Pharma UK Limited, a United Kingdom company, which was formed in 2009, is our indirectly owned subsidiary. As used in this prospectus, the term "OncoGenex" refers to our business prior to August 1, 2017.

The Offering	
Class A Units offered by us	We are offering 9,577,504 Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants).
Offering price per Class A Unit	$0.60
Class B Units offered by us	We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, 6,256 Class B Units. Each Class B Unit consists of one share of Series B Preferred Stock, par value $0.001 per share, convertible into a number of shares of common stock equal to 1,666 and a warrant to purchase 1,666 shares of our common stock (together with the shares of our common stock underlying such shares of Series B Preferred Stock and warrants).
Offering price per Class B Unit	$999.60
Overallotment option	The underwriters have the option to purchase up to 3,000,000 additional shares of common stock, and/or warrants to purchase up to 3,000,000 shares of common stock solely to cover overallotments, if any, at the price to the public less the underwriting discounts and commissions. The overallotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriters, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series B Preferred Stock) and warrants sold in the primary offering. The overallotment option is exercisable for 45 days from the date of this prospectus.
Description of warrants	The warrants will be exercisable beginning on the date of issuance and expire on the five (5) year anniversary of the date of issuance at an initial exercise price per share equal to $0.60, subject to appropriate adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect, provided, however, in no event will the exercise price per share of the warrants be reduced to an amount less than $0.06 per share of common stock (subject to adjustment for stock splits and stock combinations), or in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.

Description of Series B Preferred Stock	Each share of Series B Preferred Stock is convertible at any time at the holder's option into 1,666 shares of common stock. Notwithstanding the foregoing, we shall not effect any conversion of Series B Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series B Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see "Description of Securities — Preferred Stock."
Shares of common stock outstanding after this offering	17,680,268 shares
Shares of Series B Preferred Stock outstanding after this offering	6,256 shares
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $10.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the sale of the units to fund the development of cytisine and for working capital and general corporate purposes. We may also use a portion of the net proceeds for the acquisition of, or investment in, technologies, intellectual property or businesses that complement our business, although we have no present commitments or agreements to this effect. See "Use of Proceeds."
Risk factors	You should carefully read and consider the information set forth under "Risk Factors" in this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.
Nasdaq Capital Market common stock symbol	ACHV
No listing of Series B Preferred Stock or warrants	We do not intend to apply for listing of the shares of the Series B Preferred Stock or warrants on any securities exchange or trading system.

The number of shares of Common Stock that will be outstanding after this offering is based on 8,102,764 shares outstanding as of September 30, 2019, and excludes:

- 30,422,496 shares of our common stock that may be issued upon the conversion of shares of Series B Preferred Stock and the exercise of warrants issued in this offering;
- 1,010,935 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019, with a weighted average exercise price of $10.90 per share;
- 10,008 shares of common stock subject to restricted stock units outstanding as of September 30, 2019;

- 4,116,712 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2019, with a weighted average exercise price of $4.22 per share; and
- 604,055 shares of common stock reserved for future issuance under our equity incentive plans as of September 30, 2019.

Unless otherwise noted, the information in this prospectus assumes no exercise of outstanding options and warrants, and no exercise of the underwriters' overallotment option to purchase additional shares of common stock and/or warrants.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding to invest in our securities, you should consider carefully the risks and uncertainties described below and under Item 1A."Risk Factors" in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, or SEC, on November 6, 2019, which is incorporated by reference in this prospectus, together with all of the other information contained in this prospectus and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business.

Risks Related to Our Financial Condition and Capital Requirements

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidate.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. We have expended and continue to expend substantial funds in connection with our product development, clinical trial and regulatory approval activities.

In addition, we expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, and seek regulatory approval for, cytisinicline and add personnel necessary to operate as a public company with an advanced clinical candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidate. The current financing environment in the United States, particularly for biotechnology companies like us, is exceptionally challenging and we can provide no assurances as to when such environment will improve. For these reasons, among others, we cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders. If adequate financing is not available, we may need to continue to reduce or eliminate our expenditures for research and development of cytisinicline, and may be required to suspend development of cytisinicline. Our actual capital requirements will depend on numerous factors, including:

- our commercialization activities and arrangements;
- the progress and results of our research and development programs;
- the progress of our non-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals for our product candidate;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights with respect to our intellectual property;
- the effect of competing technological and market developments;
- the effect of changes and developments in our existing collaborative, licensing and other relationships; and

- the terms of any new collaborative, licensing, commercialization and other arrangements that we may establish.

We may not be able to secure sufficient financing on acceptable terms, or at all. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occur, our ability to achieve our development and commercialization goals would be adversely affected.

We have incurred losses since inception, have a limited operating history on which to assess our business and anticipate that we will continue to incur losses for the foreseeable future. We have never had any products available for commercial sale and we may never achieve or sustain profitability.

We are a clinical development-stage specialty pharmaceutical company with a limited operating history, are not profitable, have incurred losses in each year since our inception and do not expect to become profitable in the foreseeable future. We have never had any products available for commercial sale, and we have not generated any revenue from product sales, nor do we anticipate that we will generate revenue from product sales in the near future.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have devoted substantially all of our financial resources to identify, acquire, and develop cytisinicline, including providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and convertible promissory notes. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We further expect that our expenses will increase substantially if and as we:

- continue the clinical development of cytisinicline;
- advance cytisinicline development into larger, more expensive clinical trials;
- initiate additional non-clinical, clinical, or other trials or studies for cytisinicline;
- seek to attract and retain skilled personnel;
- undertake the manufacturing of cytisinicline or increase volumes manufactured by third parties;
- seek regulatory and marketing approvals and reimbursement for cytisinicline;
- make milestone, royalty or other payments under third-party license and/or supply agreements;
- establish a sales, marketing, and distribution infrastructure to commercialize any product for which we may obtain marketing approval and market for ourselves;
- seek to discover, identify, assess, acquire, and/or develop other product candidates;
- seek to establish, maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential for regulatory approval of cytisinicline such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that aperiod-to-period comparison of our results of operations may not be a good indication of our future performance.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals

necessary to commercialize cytisinicline. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of cytisinicline;
- obtaining regulatory and marketing approvals for cytisinicline;
- manufacturing product and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, satisfy regulatory requirements and meet our supply needs in sufficient quantities to satisfy market demand for cytisinicline, if approved;
- marketing, launching and commercializing any product for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- obtaining reimbursement or pricing for cytisinicline that supports profitability;
- gaining market acceptance of cytisinicline as a treatment option;
- addressing any competing products, including the potential for generic cytisinicline products;
- protecting and enforcing our intellectual property rights, if any, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, commercialization, or other arrangements into which we may enter; and
- attracting, hiring, and retaining qualified personnel.

Even if a product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing that candidate. Additionally, if we are not able to generate sufficient revenue from the sale of any approved products to cover our operating costs, we may never become profitable. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidate may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidate in those markets.

We are dependent upon a single company for the manufacture and supply of cytisinicline.

Our single product candidate, cytisinicline, has been in-licensed from a third party. We are required to continue to contract with Sopharma AD, or Sopharma, to continue our development of, and potential commercialization of, cytisinicline pursuant to a supply agreement with Sopharma. If the supply agreement with Sopharma is terminated, we will need to develop or acquire alternative supply and manufacturing capabilities for cytisinicline, which we may not be able to do on commercially viable terms or at all.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Capital Market. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costly. In addition, it may be difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

Recently enacted comprehensive tax reform bills could increase our tax burden and adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation, the Tax Cuts and Jobs Act of 2017, that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business

interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate.

In addition, beginning in 2022, the recently enacted tax legislation will require research and experimental expenditures to be capitalized and amortized ratably over a five-year period. Any such expenditures attributable to research conducted outside the U.S. must be capitalized and amortized over a 15-year period.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the recently enacted federal tax law.

Risks Related to the Development of Our Product Candidate Cytisinicline

Cytisinicline is currently our sole product candidate and there is no guarantee that we will be able to successfully develop and commercialize cytisinicline.

We are currently dependent on the potential development of a single product candidate, cytisinicline. We are still developing our sole product candidate, and cytisinicline cannot be marketed or sold in the United States or in foreign markets until regulatory approval has been obtained from the U.S. Food and Drug Administration, or the FDA, or applicable foreign regulatory agencies. The process of obtaining regulatory approval is expensive and time consuming. The FDA and foreign regulatory authorities may never approve cytisinicline for sale and marketing, and even if cytisinicline is ultimately approved, regulatory approval may be delayed or limited in the United States or in other jurisdictions. Even if we are authorized to sell and market cytisinicline in one or more markets, there is no assurance that we will be able to successfully market cytisinicline or that cytisinicline will achieve market acceptance sufficient to generate profits. If we are unable to successfully develop and commercialize cytisinicline due to failure to obtain regulatory approval for cytisinicline, to successfully market cytisinicline, to generate profits from the sale of cytisinicline, or due to other risk factors outlined in this report, it would have material adverse effects on our business, financial condition, and results of operations as cytisinicline is currently our sole product candidate.

Results of earlier clinical trials of cytisinicline are not necessarily predictive of future results, and any advances of cytisinicline into clinical trials may not have favorable results or receive regulatory approval.

Even if our clinical trials are completed as planned, we cannot be certain that their results will be consistent with the results of the earlier clinical trials of cytisinicline. Positive results in non-clinical testing and past clinical trials with respect to the safety and efficacy of cytisinicline do not ensure that results from subsequent clinical trials will also be positive, and we cannot be sure that the results of subsequent clinical trials will replicate the results of prior clinical trials and non-clinical testing. Any such failure may cause us to abandon cytisinicline, which would negatively affect our ability to generate any product revenues.

Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trial will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

- delays in reaching agreement on acceptable terms with clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays in recruiting qualified patients in its clinical trials;
- failure by clinical sites, CROs or other third parties to adhere to clinical trial requirements;
- failure by clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- patients terminating enrollment in our clinical trials;
- adverse events or tolerability issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;
- inability to generate satisfactory non-clinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- animal toxicology issues significant enough for the FDA or other regulatory agencies to disallow investigation in humans;
- occurrence of adverse events associated with our product candidate;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of cytisinicline;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in ongoing or other planned indications for cytisinicline; and
- delays in the manufacture or packaging of sufficient quantities of cytisinicline for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for cytisinicline could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to cytisinicline, we may need to conduct additional non-clinical trials or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize cytisinicline and may harm our business and results of operations.

Cytisinicline may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by cytisinicline could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities.

Additionally, even if cytisinicline receives marketing approval, and we or others later identify undesirable side effects caused by cytisinicline, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of cytisinicline;
- regulatory authorities may require additional warnings on the cytisinicline label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of cytisinicline, even if approved, and could significantly harm our business, results of operations, and prospects.

Our product development program may not uncover all possible adverse events that patients who take cytisinicline or our other product candidates may experience. The number of subjects exposed to cytisinicline or our other product candidates and the average exposure time in the clinical development program may be inadequate to detect rare adverse events, or chance findings, that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. We cannot be fully assured that rare and severe side effects of cytisinicline will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to cytisinicline or over a significantly longer period of time. If such safety problems occur or are identified after cytisinicline reaches the market in the United States, or if such safety problems occur or are identified in foreign markets where cytisinicline is currently marketed, the FDA may require that we amend the labeling of cytisinicline or recall it, or may even withdraw approval for cytisinicline.

If the use or misuse of cytisinicline harms patients, or is perceived to harm patients even when such harm is unrelated to cytisinicline, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

The use or misuse of cytisinicline in clinical trials and the sale of cytisinicline if marketing approval is obtained, exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product. There is a risk that cytisinicline may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, during the course of treatment, patients may suffer adverse events for reasons that may be related to cytisinicline. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market cytisinicline, if any, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to cytisinicline, an investigation into such circumstance may be time-consuming or inconclusive. Such investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals cytisinicline receives or maintains. As a result, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we obtain marketing approval for cytisinicline, we will need to expand our insurance coverage to include the sale of commercial products. We cannot know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage.

Where we have provided indemnities in favor of third parties under our agreements with them, there is a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may also bring a product liability claim against us alleging that cytisinicline causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;

- an inability to commercialize, or if commercialized, a decreased demand for, cytisinicline;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenue, if any;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- increased product liability insurance rates, or inability to maintain insurance coverage in the future on acceptable terms, if at all;
- diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations.

The development of our product candidate is dependent upon securing sufficient quantities of cytisinicline from the Laburnum anagyroides plant, which grows outside of the United States in a limited number of locations.

The therapeutic component of our product candidate, cytisinicline, is derived from the seeds of the*Laburnum anagyroides* plant, which grows in the mountains of Southern Europe. We currently secure cytisinicline exclusively from Sopharma, a Bulgarian third-party supplier. Our current supply agreement with Sopharma expires on July 28, 2037, unless extended by mutual agreement of us and Sopharma. There can be no assurances that *Laburnum anagyroides* will continue to grow in sufficient quantities to meet commercial supply requirements or that the countries from which we can secure *Laburnum anagyroides* will continue to allow the exportation of cytisinicline. Sopharma currently has planted approximately 1,000 acres of *Laburnum* trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria and is in the process of planting another 750 acres. Sopharma plans to plant additional trees to manage supply for major markets. Each tree takes approximately four to six years to reach maturity for harvesting and has a productive life expectancy of 20 to 25 years. Although Sopharma has plans to plant significant numbers of additional trees, there is no guarantee that they will do so or that the trees will produce the anticipated yield of cytisinicline. In the event we are no longer able to obtain cytisinicline from Sopharma, or in sufficient quantities, we may not be able to produce our proposed products and our business will be adversely affected.

Our business may be negatively affected by weather conditions and the availability of natural resources, as well as by climate change.

In recent years, extreme weather events and changing weather patterns such as storms, flooding, drought, and temperature changes appear to have become more common. The production of cytisinicline from the *Laburnum anagyroides* plant depends on the availability of natural resources, including sufficient rainfall. Our exclusive supplier of cytisinicline, Sopharma, could be adversely affected if it experiences a shortage of fresh water due to droughts or if it experiences other adverse weather conditions. As a result of such events, we could experience cytisinicline shortages from Sopharma, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the manufacturing and other operations of Sopharma are located near earthquake fault lines in Sofia, Bulgaria. In the event of a major earthquake, we could experience business interruptions from the disruption of our cytisinicline supplies, which could have a material adverse effect on our business, financial condition and results of operations.

We may conduct clinical trials internationally, which may trigger additional risks.

If we decide to conduct clinical trials in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing,

distribution, use of data and other matters. Failure to meet such regulatory requirements could delay our clinical trials, the approval, if any, of cytisinicline by the FDA or other regulatory authorities, or the commercialization of cytisinicline, or result in higher costs or deprive us of potential product revenues.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with some programs or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Our risk of delay in product development is increased if the United States government is fully or partially shut down due to lack of continuity in funding.

Our business operations, and particularly the timing of the outcome of review of our clinical development plans for cytisinincline, are directly and indirectly affected by the operations of the United States government, including but not limited to the FDA. Any interruption in the continuity of funding of all or a part of government activities could have a significant negative effect on our business, including the timing of any proposed interactions with the FDA related to clinical development advice or ultimately any NDA filing. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the United States government has had shut downs. We cannot predict the likelihood, duration, impact, or timing of any future shutdown. There can be no assurance that if such shutdown(s) were to occur in the future, adequate funds would be available to the FDA and other U.S. government agencies to allow them to continue their activities uninterrupted. Even when funding is restored following one or more shutdowns, we cannot predict the ongoing impact of such shutdowns on our business, or the degree to which funding would be restored to the FDA or other agencies having an impact on our business.

Risks Related to Regulatory Approval of Cytisinicline and Other Legal Compliance Matters

If we do not obtain the necessary regulatory approvals in the United States and/or other countries, we will not be able to sell cytisinicline.

We will need approval from the FDA to commercialize cytisinicline in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize cytisinicline in those jurisdictions. In order to obtain FDA approval of cytisinicline, we must submit an NDA to the FDA, demonstrating that cytisinicline is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of cytisinicline or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in data that the FDA considers safe and effective for the proposed indications of cytisinicline. The FDA has substantial discretion in the product approval process. The approval process may be

delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory approval for cytisinicline. Failure to obtain approval from the FDA or comparable regulatory authorities in foreign jurisdictions to commercialize cytisinicline will leave us without saleable products and therefore without any source of revenues. In addition, the FDA may require us to conduct additional clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product or permit continued marketing, if previously approved. If conditional marketing approval is obtained, the results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. In foreign jurisdictions, the regulatory approval processes generally include the same or similar risks as those associated with the FDA approval procedures described above. We cannot be certain that we will receive the approvals necessary to commercialize cytisinicline for sale either within or outside the United States.

Even if we obtain regulatory approval for cytisinicline, we will remain subject to ongoing regulatory requirements in connection with the sale and distribution of cytisinicline.

Even if cytisinicline is approved by the FDA or comparable foreign regulatory authorities, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and the requirements of comparable foreign regulatory authorities. Compliance with such regulatory requirements will likely be costly and the failure to comply would likely result in penalties, up to and including, the loss of such approvals from the FDA or comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we, Sopharma and other contract manufacturers, if any, will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application.

Ongoing post-approval monitoring and clinical trial obligations may be costly to us and the failure to meet such obligations may result in the withdrawal of such approvals.

Any regulatory approvals that we receive for cytisinicline, if any, may be subject to limitations on the approved indicated uses for which cytisinicline may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of cytisinicline. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for cytisinicline was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees

with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and the value of us and our operating results would be adversely affected.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for cytisinicline and begin commercializing it in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or the Healthcare Reform Law, requires manufacturers of products, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary

compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Healthcare Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and its results of operations.

Healthcare legislative and executive reform measures may have a material adverse effect on our business, financial condition or results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Healthcare Reform Law was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Healthcare Reform Law, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted, or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription products, and promotes a new Medicare Part D coverage gap discount program.

On January 20, 2017, President Donald Trump issued an Executive Order to initiate the repeal of the Healthcare Reform Law and we anticipate that additional state and federal healthcare measures under the Trump administration could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for cytisinicline, or additional pricing pressures. Currently, the Healthcare Reform Law provides coverage for smoking cessation-related activities, including two counseling attempts for smoking cessation per year and medications for smoking cessation. If these provisions are repealed, in whole or in part, our business, financial condition, or results of operations could be negatively affected.

The United Kingdom is currently a member state of the European Union. However, the United Kingdom has signaled its intention to withdraw from the European Union (commonly known as Brexit). If Brexit, which is likely to occur in 2020, does occur, the United Kingdom will no longer be a member state within the European Union. Since a significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union, Brexit could materially change the regulatory framework applicable to the approval of cytisinicline, which could have a material adverse effect on us and our operations. Brexit may also result in other significant regulatory and legislative changes in the United Kingdom, which could, for example, affect the pricing of pharmaceutical products in the United Kingdom, which could in turn result in diminished

performance for us. Even if the substance of regulatory changes resulting from Brexit does not have a significant impact on our operations, it is reasonable to expect that we would incur potentially significant costs in connection with complying with any new regulations. Further, the European Medicines Agency is currently located in the United Kingdom. It is possible that Brexit would result in the relocation of the European Medicines Agency or disruption to the European Medicines Agency's review process, either of which could have an adverse effect on our operations in the United Kingdom and the European Union.

Brexit may also have adverse effects on potential customers and collaborators of ours, which could indirectly have an adverse effect on us.

Our ability to obtain services, reimbursement or funding may be impacted by possible reductions in federal spending in the United States as well as globally.

U.S. federal government agencies currently face potentially significant spending reductions. Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021 triggered automatic cuts to most federal programs. These cuts would include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was enacted on January 1, 2013, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. The full impact on our business of these automatic cuts is uncertain.

If government spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Any reductions in government spending in countries outside the United States may also impact us negatively, such as by limiting the functioning of international regulatory agencies in countries outside the United States or by eliminating programs on which we may rely.

Risks Related to our Business Operations

It is difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

To date our business activities have been focused primarily on the development and regulatory approval of cytisinicline and its various alternative forms. Although we have not generated revenue to date, we expect that, after any regulatory approval, any receipt of revenue will be attributable to sales of cytisinicline, primarily in the United States, the European Union (including the United Kingdom) and Asia. Because we devote substantially all of our resources to the development of cytisinicline and rely on cytisinicline as our sole source of potential revenue for the foreseeable future, any factors that negatively impact this product, or result in decreasing product sales, would materially and adversely affect our business, financial condition and results of operations.

Our future success depends in part on our ability to attract, retain, and motivate other qualified personnel.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. We expect to need additional scientific, technical, operational, financial and other personnel. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Richard Stewart, John Bencich, Cindy Jacobs, Anthony Clarke and Jaime Xinos. In addition, although we have entered

into employment agreements with each of Mr. Stewart, Mr. Bencich, Dr. Jacobs, Dr. Clarke and Ms. Xinos, such agreements permit those executives to terminate their employment with us at any time, subject to providing us with advance written notice.

We may not be able to attract and retain personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of cytisinicline may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of our current personnel may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We may need to expand our organization, which may require us to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in its infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Expanded growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

In the future, we may invest in the development of additional indications for cytisinicline. If we invest in and are unsuccessful in developing additional indications for cytisinicline, our business, financial condition and results of operations may be adversely affected.

In the future, we may invest in the research and development of new indications for cytisinicline to address nicotine addictions associated with the use of electronic cigarette, or vaping, products. Given their recent introduction, the use of vaping products is not fully understood which may increase the risk of failure in this area. The development of additional indications for cytisinicline is highly uncertain. During the research and development cycle, we may expend significant time and resources on developing additional indications without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of additional indications, and failure can occur at any point in the process, including late in the process after substantial investment. Further, any new indications may not be accepted by physicians and the medical community at large, and competitors may develop and market equivalent or superior products. Failure to launch commercially successful new indications for cytisinicline after significant investment could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties to manufacture cytisinicline for use in clinical trials, and we intend to exclusively rely on Sopharma to produce and process cytisinicline, if approved. Our commercialization of cytisinicline could be stopped, delayed or made less profitable if Sopharma fails to obtain approval of government regulators, fails to provide us with sufficient quantities of product, or fails to do so at acceptable quality levels or prices.

We do not currently have nor do we currently plan to develop the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture cytisinicline on a clinical or commercial scale. We currently exclusively rely on

Sopharma to manufacture cytisinicline for use in clinical trials and plan to continue relying on Sopharma to manufacture cytisinicline on a commercial scale, if approved.

Our reliance on Sopharma exposes us to the following additional risks:

- Sopharma might be unable to timely manufacture cytisinicline or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- we may be unable to identify manufacturers other than Sopharma on acceptable terms or at all;
- Sopharma may not be able to execute our manufacturing procedures appropriately;
- Sopharma may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Sopharma is or will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with Current Good Manufacturing Practices, or cGMPs, and other government regulations and corresponding foreign standards. We do not have control over Sopharma's compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by Sopharma in the manufacturing process for cytisinicline;
- we do not own the intellectual property rights to cytisinicline, and Sopharma could license such rights to third parties or begin supplying other third parties with cytisinicline; and
- Sopharma could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of cytisinicline by the FDA or the commercialization of cytisinicline or result in higher costs or deprive us of potential product revenue.

We rely on third party contract manufacturing organizations, or CMOs, to package the cytisinicline used in our clinical trials. If any of these CMO's fail to timely deliver supplies needed then our clinical studies could be delayed materially. Third-party manufacturers may fail to perform under their contractual obligations, or may fail to deliver the required commercial product on a timely basis and at commercially reasonable prices. If we are required to identify and qualify an alternate manufacturer, we may be forced to delay or suspend our clinical trials. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in the supply of cytisinicline or in the Sopharma manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of cytisinicline will not occur in the future. Additionally, Sopharma may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or political instability in the countries in which Sopharma conducts its operations. If Sopharma were to encounter any of these difficulties, or otherwise fail to comply with its contractual obligations, our ability to provide our product candidate to patients in clinical trials could be delayed or suspended. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Similar political instability could also harm the commercial production and supply of cytisinicline in the event that cytisinicline is ultimately approved for commercial sale.

We rely on third parties to conduct our clinical trials and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize cytisinicline and our business could be substantially harmed.

We plan to rely upon third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be assured that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, continued development of cytisinicline may be delayed or terminated and we may not be able to meet our current plans with respect to cytisinicline. CROs may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize cytisinicline.

Our business plan relies heavily on third party collaborators, partners, licensees, clinical research organizations, clinical investigators, vendors or other third parties to support our research and development efforts and to conduct clinical trials for cytisinicline. We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, these third parties on a commercially reasonable basis, if at all. If we fail to establish or maintain such third-party relationships as anticipated, our business could be adversely affected.

We may be unable to realize the potential benefits of any collaborations which we may enter into with other companies for the development and commercialization of cytisinicline.

We may enter into a collaboration with third parties concerning the development and/or commercialization of cytisinicline; however, there is no guarantee that any such collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of cytisinicline;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to cytisinicline, or other potential products or proprietary technologies or grant licenses on terms that are not favorable to us;

- collaborators may cease to devote resources to the development or commercialization of cytisinicline if the collaborators view cytisinicline as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of cytisinicline, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of cytisinicline.

As a result, a collaboration may not result in the successful development or commercialization of cytisinicline.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Cytisinicline

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The development and commercialization of new products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to cytisinicline and the other product candidates that we may seek to develop or commercialize in the future. We are aware that many companies have therapeutics marketed or in development for smoking cessation, including, Pfizer Inc., GlaxoSmithKline Plc, Merck & Co., Novartis, Pharmacia Polonica, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, zpharm, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm, Adamed, Aflofarm, Axsome, Smoke Free Therapeutics, Antidote Therapeutics and others.

Many of our competitors have substantially greater financial, name recognition, manufacturing, marketing, research, technical and other resources than us. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Further, our competitors may develop new products that are safer, more effective or more cost-efficient than cytisinicline. Large pharmaceutical companies in particular have extensive expertise in non-clinical and clinical testing and in obtaining regulatory approvals for products. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure of cytisinicline to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

The commercial success of cytisinicline will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Failure to obtain or maintain adequate reimbursement or insurance coverage for products, if any, could limit our ability to market cytisinicline and decrease our ability to generate revenue.

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of cytisinicline will depend in part on the healthcare providers, patients, and third-party payors accepting cytisinicline as medically useful, cost-effective, and safe. Cytisinicline may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of cytisinicline will depend on a number of factors, including but not limited to:

- the safety and efficacy, if any, of cytisinicline as demonstrated in clinical trials and potential advantages over competing treatments, if any;
- the clinical indications for which approval is granted, if any, including any limitations or warnings contained in cytisinicline's approved labeling;
- the cost of treatment;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend the product to patients based on such risks and benefits;
- the marketing, sales and distribution support for cytisinicline;
- the publicity concerning cytisinicline or competing products and treatments;
- the pricing and availability of third-party insurance coverage and reimbursement;
- negative perceptions or experiences with our competitor's products may be ascribed to cytisinicline; and
- availability of cytisinicline from other suppliers and/or distributors.

Even if cytisinicline displays a favorable efficacy and safety profile upon approval, market acceptance of cytisinicline remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of cytisinicline, if any, may require significant investment and resources and may never be successful. Additionally, third-party payors, including governmental and private insurers, may also encourage the use of generic products instead of cytisinicline, or a generic version of cytisinicline, which require a prescription. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other healthcare providers, we will not be able to generate sufficient revenue to become or remain profitable.

The pricing, coverage, and reimbursement of cytisinicline, if any, must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford treatments. Sales of cytisinicline, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of cytisinicline will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide cytisinicline for free or we may not be able to successfully commercialize cytisinicline.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new products are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as cytisinicline and what reimbursement codes cytisinicline may receive if approved.

Outside the United States, selling operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription products has and is expected to continue to increase in the future. As a result, profitability of cytisinicline, if any, may be more difficult to achieve even if regulatory approval is received.

Sopharma may breach its supply agreement with us and sell cytisinicline into our territories or permit third parties to export cytisinicline into our territories and negatively affect our commercialization efforts of our products in our territories.

We are currently dependent on the exclusivity provisions of our supply agreement with Sopharma to conduct our business and to prevent Sopharma from competing, directly and indirectly, with us in the United States and Western Europe. If Sopharma were to breach the exclusivity provisions of the supply agreement with us and sell or distribute cytisinicline directly into our territories or permit third parties to export cytisinicline into our territories, among other things, the increase in competition within our anticipated markets could have a material adverse effect on our business, results of operations and financial condition.

The illegal distribution and sale by third parties of counterfeit versions of cytisinicline, stolen products, or alternative third party distribution and sale of cytisinicline could have a negative impact on our financial performance or reputation.

Cytisinicline is not patentable in the United States as it is a naturally occurring substance. As such, third parties are able to manufacture, sell or distribute cytisinicline without royalties or other payments to us and compete with our products in the United States and potentially worldwide and negatively impact our commercialization efforts of our products. We are aware of additional cytisinicline products approved in several European countries and we may not be able to block other third parties from launching generic versions of cytisinicline. Third parties may also sell or distribute cytisinicline as an herbal or homeopathic product. Other than regulatory exclusivity or other limitations, there may be little to nothing to stop these third parties from manufacturing, selling or distributing cytisinicline. Because we have no ability to set rigorous safety standards or control processes over third party manufacturers, sellers or distributors of cytisinicline, excluding Sopharma, these formulations of cytisinicline may be unsafe or cause adverse effects to patients and negatively impact the reputation of cytisinicline as a safe and effective smoking cessation aid.

Third parties could illegally distribute and sell counterfeit versions of cytisinicline, especially on online marketplaces, which do not meet the rigorous manufacturing and testing standards under cGMP. Counterfeit products are frequently unsafe or ineffective, and may even be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient or no active pharmaceutical ingredients at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe cytisinicline products could materially affect patient confidence in our cytisinicline product. It is possible that adverse events caused by unsafe counterfeit or other non-Achieve cytisinicline products will mistakenly be attributed to our cytisinicline product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation, and our business. Public loss of confidence in the integrity in cytisinicline as a result of counterfeiting, theft, or improper manufacturing processes could have a material adverse effect on our business, results of operations, and financial condition.

It is illegal to sell unapproved prescription medicines in the United States. Sopharma's cytisinicline brand, Tabex, is currently approved for sale in certain Central and Eastern European countries. Cytisinicline has not yet received a marketing approval from the FDA or the European Medicines Agency, and we intend to conduct the requisite clinical trials to obtain approval for the marketing of cytisinicline in the United States and in Europe. We are aware that products purporting to be Tabex are available, via third party internet sites, for importation in the United States and other global markets. We have no control over the authenticity of products purchased through these sites, which may be counterfeit or sourced from distributors in Central and Eastern Europe without authorization to sell into the United States or European Union.

We may attempt to form collaborations in the future with respect to cytisinicline, but we may not be able to do so, which may cause us to alter our development and commercialization plans.

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for cytisinicline on terms that are acceptable to us, or at all. This may be because cytisinicline may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, or cytisinicline's patent protection insufficient, and/or third parties may not view cytisinicline as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaborators and entering into agreements to develop and/or commercialize cytisinicline could delay the development or commercialization of cytisinicline, which may reduce our competitiveness even if we reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidate cytisinicline or bring it to market and our business may be materially and adversely affected.

We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates.

Although a substantial amount of our effort will focus on clinical testing, approval, and potential commercialization of cytisinicline, our sole product candidate, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our potential product candidates may not succeed innon-clinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a potential product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a potential product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations.

Risks Related to our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to cytisinicline, product compounds and processes for our development pipeline through acquisitions and in-licenses.

Presently, we have rights to the intellectual property through trade secrets, licenses from third parties and patent applications that we own. Our product candidate may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we are unable to maintain effective proprietary rights for our product candidate or any future product candidates, we may not be able to compete effectively in our proposed markets.

We currently rely primarily on trade secret protection and on confidentiality agreements to protect proprietaryknow-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets can be difficult to protect, however, and even where they are protected they generally provide less intellectual property protection to the holder of the trade secret than to a holder of a patent. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

We are currently developing cytisinicline for smoking cessation. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. We are not aware of any patents or patent applications that would prevent the development, manufacture or marketing of cytisinicline for smoking cessation.

We are aware of U.S. and foreign patents and pending patent applications owned by third parties that cover certain other therapeutic uses of cytisinicline. We are currently monitoring these patents and patent applications. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications for these certain additional therapeutic uses. If any third-party patents or patent applications cover our product candidates or technologies in other therapeutic uses, we may not be free to manufacture or market our product candidates for additional therapeutic uses, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we

may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidate may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We intend to rely on patent rights for certain aspects of our product candidates and certain future product candidates. If we are unable to obtain or maintain an adequate proprietary position from this approach, we may not be able to compete effectively in our markets.

Although we rely or will rely primarily on trade secret protection as part of our intellectual property rights strategies, we also intend to rely on patent rights to protect certain aspects of our technologies and upon the patent rights of third parties from which we license certain of our technologies.

We have sought to protect our proprietary position by filing patent applications in the United Kingdom, United States and certain other countries around the world related to future product candidates. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patent applications or our patents (once issued) have been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our future product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our future product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any future product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a future product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office, or the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

In a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc*., the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Cytisinicline is a naturally-occurring product and is not patentable. Our intellectual property strategy involves novel formulations of cytisinicline and there is no guarantee that such patents will be issued or if issued, will be broad enough to prevent competitors from developing competing cytisinicline products. Although we do not believe that any patents that may issue from our pending patent applications directed at our product candidate, if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we have written agreements and make every effort to ensure that our employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Our Common Stock

The price for our common stock is volatile.

The market prices for our common stock and that of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to raise additional capital, the terms of such capital, and our ability to continue as a going concern;

- the ability of us or our partners to develop cytisinicline and other product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of us or our partners to obtain regulatory approvals for cytisinicline or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure to maintain our existing third-party license, manufacturing and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about us, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock us or our stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of healthcare payment systems;
- period-to-period fluctuations in our financial results; and
- tweets or other social media posts related to our market and industry.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. An increase in the market price of our common stock, which is uncertain and unpredictable, may be the sole source of gain from an investment in our common stock. An investment in our common stock may not be appropriate for investors who require dividend income. We have never declared or paid cash dividends on our capital stock and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for stockholders for the foreseeable future. Accordingly, an investment in our common stock may not be appropriate for investors who require dividend income or investors who are not prepared to bear a significant risk of losses from such an investment.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, including in circumstances where such declines occur in close proximity to the announcement of clinical trial results. Additionally, our stock price and those of other biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such

litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Because our recent merger resulted in an ownership change under Section 382 of the U.S. Internal Revenue Code for OncoGenex,pre-merger net operating loss carryforwards and certain other tax attributes are now subject to limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the U.S. Internal Revenue Code, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our recent merger involving OncoGenex and Achieve Life Sciences, Inc. resulted in an ownership change for OncoGenex and, accordingly, OncoGenex's net operating loss carryforwards and certain other tax attributes will be subject to limitations on their use after the merger. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Anti-takeover provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The sale of additional shares of common stock pursuant to our existing equity sale agreements may cause the price of our common stock to decline and result in dilution to our existing stockholders.

In September 2017 we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or LPC, we have the right, from time to time, in our sole discretion and subject to certain conditions, to direct LPC to purchase additional shares of common stock having an aggregate value of $10.0 million and we

have exercised this right. We have directed LPC to purchase additional shares and may further direct LPC to purchase additional shares as often as every business day over the 30-month term of the Purchase Agreement in increments of up to 80,000 shares of common stock, with such amounts increasing as the closing sale price of our common stock increases. The purchase price of shares of common stock pursuant to the Purchase Agreement have been and will be based on prevailing market prices of common stock at the time of sale without any fixed discount, and we have controlled and will control the timing and amount of any sales of common stock to LPC. In addition, we have directed and we may direct LPC in the future to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below $2.00 per share.

In June 2019 we entered into an at-the-market offering agreement, the Offering Agreement, with H.C. Wainwright & Co., or H.C. Wainwright. Pursuant to the terms of the Offering Agreement, we may offer and sell, from time to time through H.C. Wainwright, shares of our common stock having an aggregate offering price of up to $6.0 million. We will control the timing and amount of any sales of common stock under the Offering Agreement. Under the terms of the Offering Agreement, H.C. Wainwright may sell the shares our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers' transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. We have not offered any shares of our common stock for sale pursuant to the Offering Agreement, but could do so in the future.

The sale of additional shares of our common stock pursuant to our purchase agreement with LPC or the Offering Agreement has or will have a dilutive impact on our existing stockholders. Sales by us to LPC or by H.C. Wainwright under the Offering Agreement could cause the market price of our common stock to decline significantly. Sales of our common stock under the purchase agreement or the Offering Agreement, or the perception that such sales will occur, could also encourage short sales by third parties, which could contribute to the further decline of our stock price. Additionally, the sale of a substantial number of shares of our common stock under the purchase agreement or the Offering Agreement, or the perception that such sales will occur, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish.

If we raise additional capital, the terms of the financing transactions may cause dilution to existing stockholders or contain terms that are not favorable to us.

In the future, we plan to raise additional capital through private placements or public offerings of our equity or debt securities. We cannot be certain that additional funding will be available on acceptable terms, if at all. To the extent that we raise additional financing by issuing equity securities, we may do so at a price per share that represents a discount to the then-current per share trading price of our common stock and our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934, and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in our SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to This Offering

Management will have broad discretion as to the use of proceeds from this offering and we may use the net proceeds in ways with which you may disagree.

We intend to use the net proceeds of this offering to fund the development of cytisine and for working capital and general corporate purposes. We may also use a portion of the net proceeds for the acquisition of, or investment in, technologies, intellectual property or businesses that complement our business, although we have no present commitments or agreements to this effect. Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Accordingly, you will be relying on the judgment of our management on the use of net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of our common stock you purchase in this offering. Based on a public offering price of $0.60 per share, purchasers of common stock in this offering will experience immediate dilution of $0.04 per share in net tangible book value of our common stock. In the past, we issued options, warrants and other securities to acquire common stock at prices below the public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See "Dilution" for a more detailed description of the dilution to new investors in the offering.

The offering price will be set by our Board of Directors and does not necessarily indicate the actual or market value of our common stock.

Our Board of Directors will approve the offering price and other terms of this offering after considering, among other things: the number of shares authorized in our certificate of incorporation; the current market price of our common stock; trading prices of our common stock over time; the volatility of our common stock; our current financial condition and the prospects for our future cash flows; the availability of and likely cost of capital of other potential sources of capital; and market and economic conditions at the time of the offering. The offering price is not intended to bear any relationship to the book value of our assets or our past operations, cash flows, losses, financial condition, net worth or any other established criteria used to value securities. The offering price may not be indicative of the fair value of the common stock.

The Series B Preferred Stock is an unlisted security and there is no public market for it.

There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, the Series B Preferred Stock is not listed, and we do not intend to apply for listing of the Series B Preferred Stock on any securities exchange or trading system. Without an active market, the liquidity of the Series B Preferred Stock is limited, and investors may be unable to liquidate their investments in the Series B Preferred Stock.

The warrants may not have any value.

The warrants will be exercisable for five years from the closing date at an initial exercise price per share of $0.60. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

The warrants are subject to an issuer call.

If, after the date that is 180 days after the closing date, (i) the volume weighted average price for each of 30 consecutive trading days, or Measurement Period, which Measurement Period commences after the date that is 180 days after the closing date, exceeds 300% of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like after the initial exercise date), (ii) the average daily volume for such Measurement Period exceeds $500,000 per trading day and, (iii) the warrant holder is not in possession of any material non-public information which was provided by the Company, then the Company may, within one trading day of the end of such Measurement Period, call for cancellation of all or any portion of the warrants for which an exercise notice has not yet been delivered for consideration equal to $0.001 per warrant share. The Company's right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants. You may be unable to reinvest your proceeds from the call in an investment with a return that is as high as the return on the warrants would have been if they had not been called.

A warrant does not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your warrants, the warrants will not provide you any rights as a common stockholder. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "could," "plan," "intend," or similar expressions in this prospectus or in documents incorporated by reference into this prospectus. We intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- our ability to continue as a going concern, our anticipated future capital requirements and the terms of any capital financing agreements;
- progress and preliminary and future results of any clinical trials;
- anticipated regulatory filings, requirements and future clinical trials;
- timing and amount of future contractual payments, product revenue and operating expenses; and
- market acceptance of our products and the estimated potential size of these markets.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include the risk factors identified under the caption "Risk Factors" in this prospectus, as well as those identified under Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2019.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $10.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their overallotment option in full, we estimate that our net proceeds will be approximately $12.4 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any additional proceeds from any future conversions of the Series B Preferred Stock. We will only receive additional proceeds from the exercise of the warrants issuable in connection with this offering if the warrants are exercised and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the warrants.

We intend to use net proceeds from this offering to fund the development of cytisine and for working capital and general corporate purposes. We may also use a portion of the net proceeds for the acquisition of, or investment in, technologies, intellectual property or businesses that complement our business, although we have no present commitments or agreements to this effect. We have not yet determined the amount of net proceeds to be used specifically for any particular purpose or the timing of these expenditures. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities.

MARKET FOR COMMON EQUITY AND DIVIDEND POLICY

Market Information and Holders of Record

Our common stock trades on The Nasdaq Capital Market under the symbol "ACHV." The last reported sale price for our common stock on December 16, 2019 was $0.77 per share. As of December 16, 2019, we had approximately 16 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. A description of the common stock that we are issuing in this offering is set forth under the heading "Description of Securities."

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

We will not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as we pay dividends on each share of Series B Preferred Stock on an as-converted basis. Other than as set forth in the previous sentence, no other dividends will be paid on the Series B Preferred Stock and we will pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 30, 2019:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of 9,577,504 Class A Units and 6,256 Class B Units in this offering, based on an offering price of $0.60 per Class A Unit and $999.60 per Class B Unit, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q filed with the SEC on November 6, 2019 and with our consolidated financial statements and the accompanying notes, which are incorporated by reference in this prospectus.

	As of September 30, 2019	
	Actual	As Adjusted
	(In thousands, except share data)	
Cash and cash equivalents	$ 7,375	$ 18,107
Stockholders' equity (deficit)		
Preferred Stock, par value $0.001 per share; 5,000,000 shares authorized; no shares issued and outstanding actual, 6,256 shares issued and outstanding as adjusted as of September 30, 2019	—	—
Common Stock, par value $0.001 per share; 150,000,000 shares authorized; 8,102,764 shares issued and outstanding actual, 17,680,268 shares issued and outstanding as adjusted as of September 30, 2019	19	29
Additional paid-in capital	50,628	61,351
Accumulated deficit	(42,510)	(42,510)
Accumulated other comprehensive income	4	4
Total stockholders' equity	8,141	18,874
Total capitalization	8,141	18,874

The number of shares of Common Stock that will be outstanding after this offering is based on 8,102,764 shares outstanding as of September 30, 2019, and excludes:

- 30,422,496 shares of common stock that may be issued upon the conversion of shares of Series B Preferred Stock and the exercise of warrants issued in this offering;
- 1,010,935 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019, with a weighted average exercise price of $10.90 per share;
- 10,008 shares of common stock subject to restricted stock units outstanding as of September 30, 2019;
- 4,116,712 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2019, with a weighted average exercise price of $4.22 per share; and
- 604,055 shares of common stock reserved for future issuance under our equity incentive plans as of September 30, 2019.

DILUTION

Our net tangible book value as of September 30, 2019 was approximately $5.0 million, or approximately $0.61 per share of common stock based on 8,102,764 shares outstanding. Net tangible book value per share is determined by dividing our net tangible book value, which consists of tangible assets less total liabilities, by the number of shares of common stock outstanding on that date.

After giving effect to the effect to the sale of 9,577,504 Class A Units and 6,256 Class B Units in this offering, based on an offering price of $0.60 per Class A Unit and $999.60 per Class B Unit, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, and assuming the conversion of all of the shares of Series B Preferred Stock to common stock at a conversion rate of 1,666 shares of common stock for each share of Series B Preferred Stock, we would have had a net tangible book value as of September 30, 2019 of approximately $15.7 million, or $0.56 per share of common stock. This represents an immediate decrease in the net tangible book value of $0.05 per share to our existing stockholders and an immediate dilution in net tangible book value of $0.04 per share to the investor in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock		$ 0.60
Net tangible book value per share as of September 30, 2019	$ 0.61	
Decrease in net tangible book value per share attributable to the offering	(0.05)	
As adjusted net tangible book value per share after giving effect to the offering		0.56
Dilution in net tangible book value per share to new investor		$ 0.04

The table above excludes:

- 30,422,496 shares of common stock that may be issued upon the exercise of warrants issued in this offering;
- 1,010,935 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2019, with a weighted average exercise price of $10.90 per share;
- 10,008 shares of common stock subject to restricted stock units outstanding as of September 30, 2019;
- 4,116,712 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2019, with a weighted average exercise price of $4.22 per share; and
- 604,055 shares of common stock reserved for future issuance under our equity incentive plans as of September 30, 2019.

SECURITY OWNERSHIP OF BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of September 30, 2019, for:

(1) each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;

(2) each of our named executive officers;

(3) each of our directors; and

(4) all current executive officers and directors as a group.

Applicable percentage ownership is based on 8,102,764 shares of common stock outstanding at September 30, 2019. We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options or warrants, or the conversion of convertible notes, held by the respective person or group that may be exercised or converted within 60 days after September 30, 2019. For purposes of calculating each person's or group's percentage ownership, stock options and warrants exercisable, and notes convertible, within 60 days after September 30, 2019 are included for that person or group, but not the stock options of any other person or group.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each person listed in the table is c/o Achieve Life Sciences, Inc., 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership(1)	Percent of Class(%)(1)
5% or Greater Stockholders:		
Sio Capital Management, LLC(2)	597,373	7.37
UBS Group AG(3)	453,012	5.59
Named Executive Officers and Directors:		
Richard Stewart(4)	294,304	3.63
Anthony Clarke(5)	130,138	1.60
Scott Cormack(6)	17,954	*
Cindy Jacobs(7)	40,906	*
John Bencich(8)	45,079	*
Martin Mattingly(9)	13,650	*
Stewart Parker(10)	13,629	*
Donald Joseph(11)	13,226	*
Jay Moyes(12)	13,226	*
All current officers and directors as a group (9 persons)(13)	582,112	7.18

* Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options and warrants currently exercisable, or exercisable within 60 days of September 30, 2019, are deemed outstanding for computing the percentage of the person holding such options or warrants but are not deemed outstanding for computing the percentage of any other person.

(2) Based solely on a Schedule 13G filed by Sio Capital Management, LLC ("SIO") on February 14, 2019, reflecting beneficial ownership as of December 31, 2018. Sio reported it is the registered investment advisor

of certain affiliated funds that directly hold 597,373 shares of common stock for the benefit of their respective investors, and in such capacity, Sio has voting and dispositive power over such shares. Sio's investment discretion with respect to such shares is subject to oversight by Sio GP, LLC ("Sio GP"). Accordingly, Sio GP may be deemed to be the beneficial owner of such shares. Sio and Sio GP are controlled by Michael Castor. Accordingly, Michael Castor may be deemed to control the voting and dispositive decisions with respect to, and therefore be the beneficial owner of, such shares. The address for Sio is 535 Fifth Avenue, Suite 910, New York, New York 10017.

(3) Based solely on a Schedule 13G filed by UBS Group AG on February 14, 2019, representing beneficial ownership as of December 31, 2018. Representing 453,012 shares of common stock beneficially owned by UBS Group AG on behalf of itself and its wholly-owned subsidiaries UBS AG London Branch and UBS Securities LLC, over which it had shared voting and dispositive power. The address for UBS Group AG is Bahnhofstrasse 45, PO Box CH-8098.

(4) Represents 212,530 shares owned directly, 56,947 options exercisable within 60 days of September 30, 2019, 7,186 owned indirectly through his partner and 17,641 shares owned indirectly through Ricanto Limited as a principal owner.

(5) Represents 55,045 shares owned directly, 21,522 options exercisable within 60 days of September 30, 2019, 35,930 shares owned indirectly through his spouse, and 17,641 shares owned indirectly through Ricanto Limited as a principal owner.

(6) Represents 1,481 shares owned directly, 15,505 options exercisable within 60 days of September 30, 2019, and 968 shares owned indirectly through his spouse.

(7) Represents 2,801 shares owned directly and 38,105 options exercisable or vesting within 60 days of September 30, 2019.

(8) Represents 2,101 shares owned directly and 42,978 options exercisable or vesting within 60 days of September 30, 2019.

(9) Represents 94 shares owned directly and 13,556 options exercisable within 60 days of September 30, 2019.

(10) Represents 117 shares owned directly and 13,512 options exercisable within 60 days of September 30, 2019.

(11) Represents 13,226 options exercisable within 60 days of September 30, 2019.

(12) Represents 13,226 options exercisable within 60 days of September 30, 2019.

(13) Represents for the current officers and directors as a group, 335,894 shares owned directly or indirectly as indicated above, and 228,577 options exercisable or vesting within 60 days of September 30, 2019.

DESCRIPTION OF SECURITIES

Units

We are offering 9,577,504 Class A Units, with each Class A Unit consisting of one share of common stock and a warrant to purchase one share of our common stock at an exercise price per share of $0.60, together with the shares of common stock underlying such warrants, at a public offering price of $0.60 per Class A Unit. The Class A Units will not be certificated and the shares of common stock and warrants part of such units are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%), 6,256 Class B Units. Each Class B Unit consists of one share of Series B Preferred Stock, par value $0.001 per share, convertible into 1,666 shares of common stock and a warrant to purchase 1,666 shares of our common stock at an exercise price per share of $0.60, together with the shares of common stock underlying such shares of Series B Preferred Stock and warrants, at a public offering price of $999.60 per Class B Unit. The Class B Units will not be certificated and the shares of Series B Preferred Stock and the warrants part of such units are immediately separable and will be issued separately in this offering.

Description of Capital Stock

The following description of our common stock and preferred stock summarizes the material terms and provisions of the common stock and preferred stock that we may issue in connection with this offering. It may not contain all the information that is important to you. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation, as amended and restated, and our amended and restated bylaws, which were filed as exhibits to the registration statement of which this prospectus forms a part.

Common Stock

Under our restated certificate of incorporation, as of September 30, 2019, we had authority to issue 150,000,000 shares of our common stock, par value $0.001 per share. As of September 30, 2019, 8,102,764 shares of our common stock were issued and outstanding. All shares of our common stock will, when issued, be duly authorized, fully paid and nonassessable.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of our common stock is entitled to one vote for each share registered in his or her name. Except as may be required by law and in connection with some significant actions, such as mergers, consolidations, or amendments to our certificate of incorporation that affect the rights of stockholders, holders of our common stock vote together as a single class. There is no cumulative voting in the election of our directors, which means that, subject to any rights to elect directors that are granted to the holders of any class or series of preferred stock, a plurality of the votes cast at a meeting of stockholders at which a quorum is present is sufficient to elect a director.

Liquidation. In the event we are liquidated, dissolved or our affairs are wound up, after we pay or make adequate provision for all of our known debts and liabilities, each holder of our common stock will be entitled to share ratably in all assets that remain, subject to any rights that are granted to the holders of any class or series of preferred stock.

Dividends. Subject to preferential dividend rights of any other class or series of stock, the holders of shares of our common stock are entitled to receive dividends, including dividends of our stock, as and when declared by our board of directors, subject to any limitations imposed by law and to the rights of the holders, if any, of our preferred stock. We have never paid cash dividends on our common stock. We do not anticipate paying periodic cash dividends on our common stock for the foreseeable future. Any future determination about the payment of

dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as the board of directors deems relevant.

Other Rights and Restrictions. Subject to the preferential rights of any other class or series of stock, all shares of our common stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by Delaware law. Furthermore, holders of our common stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our certificate of incorporation and our bylaws do not restrict the ability of a holder of our common stock to transfer his or her shares of our common stock.

The rights, powers, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock which we may designate and issue in the future.

Listing. Our common stock is listed on The Nasdaq Capital Market under the symbol "ACHV."

Transfer Agent and Registrar. The transfer agent for our common stock is American Stock Transfer & Trust Company, LLC.

Preferred Stock

Under our restated certificate of incorporation, we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. In June 2018 we issued 9,158 shares of Series A Convertible Preferred Stock, all of which have been converted into shares of our common stock. As of September 30, 2019, no shares of preferred stock were issued and outstanding.

Pursuant to our restated certificate of incorporation, we are authorized to issue "blank check" preferred stock, which may be issued from time to time in one or more series upon authorization by our board of directors. Our board of directors, without further approval of the stockholders, is authorized to fix the designation, powers, preferences, relative, participating optional or other special rights, and any qualifications, limitations and restrictions applicable to each series of the preferred stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes could, among other things, adversely affect the voting power or rights of the holders of our common stock and, under certain circumstances, make it more difficult for a third party to gain control of us, discourage bids for our common stock at a premium or otherwise adversely affect the market price of the common stock.

Description of the Series B Preferred Stock Included in the Class B Units

In connection with this offering, our board of directors will designate shares of our preferred stock as Series B Preferred Stock. The preferences and rights of the Series B Preferred Stock will be as set forth in a Certificate of Designation, or Series B Certificate of Designation, filed as an exhibit to the registration statement of which this prospectus forms a part.

In the event of a liquidation, the holders of Series B Preferred Stock will be entitled to participate on anas-converted-to-common-stock basis with holders of the common stock in any distribution of assets of the Company to the holders of the common stock. The Series B Certificate of Designation will provide, among other things, that we shall not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as we pay dividends on each share of Series B Preferred Stock on an as-converted basis. Other than as set forth in the previous sentence, the Series B Certificate of Designation will provide that no other dividends shall be paid on shares of Series B Preferred Stock and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence. The Series B Certificate of Designation will not provide for

any restriction on the repurchase of Series B Preferred Stock by us while there is any arrearage in the payment of dividends on the Series B Preferred Stock. There will be no sinking fund provisions applicable to the Series B Preferred Stock.

With certain exceptions, as described in the Series B Certificate of Designation, the Series B Preferred Stock will have no voting rights. However, as long as any shares of Series B Preferred Stock remain outstanding, the Series B Certificate of Designation will provide that we shall not, without the affirmative vote of holders of a majority of the then-outstanding shares of Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Series B Certificate of Designation, (b) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock , (c) increase the number of authorized shares of Series B Preferred Stock, (c) effect a stock split or reverse stock split of the Series B Preferred Stock or any like event or (d) enter into any agreement with respect to any of the foregoing.

Each share of Series B Preferred Stock will be convertible at any time at the holder's option into 1,666 shares of common stock, which conversion ratio will be subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series B Certificate of Designation will further provide that we shall not effect any conversion of the Series B Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series B Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Preferred Stock Beneficial Ownership Limitation").

Additionally, subject to certain exceptions, at any time prior to the three year anniversary of the issuance of the Series B Preferred Stock, subject to the Preferred Stock Beneficial Ownership Limitation, we will have the right to cause each holder of the Series B Preferred Stock to convert all or part of such holder's Series B Preferred Stock in the event that (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period") exceeds 300% of the conversion price of the preferred stock issued in this offering (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company and subject to the Preferred Beneficial Ownership Limitation. Our right to cause each holder of the Series B Preferred Stock to convert all or part of such holder's Series B Preferred Stock shall be exercised ratably among the holders of the then outstanding Series B Preferred Stock.

We do not intend to apply for listing of the Series B Preferred Stock on any securities exchange or other trading system.

The transfer agent for our Series B Preferred Stock will be American Stock Transfer & Trust Company, LLC.

Description of Warrants Included in the Units

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus forms a part. Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian, on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock and each Class B Unit issued in this offering includes warrants to purchase 1,666 shares of our common stock at a price equal to $0.60 per share at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised.

Subject to certain limitations as described below the warrants are immediately exercisable upon issuance on the closing date and expire on the five-year anniversary of the closing date. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise.

The exercise price of the warrants is subject to adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect provided, however, in no event will the exercise price per share of the warrants be reduced to an amount less than $0.06 per share of common stock (subject to adjustment for stock splits and stock combinations). The exercise price and the number of shares issuable upon exercise of the warrants is also subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants. On the expiration date, unexercised warrants will automatically be exercised via the "cashless" exercise provision.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of such warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants. Additionally, as more fully described in the warrants, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the warrants on the date of consummation of such transaction.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement, of which this prospectus forms a part, effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a "cashless" exercise provision).

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding, if, after the closing date, (i) the volume weighted average price of our common

stock for each of 30 consecutive trading days (the "Measurement Period"), which Measurement Period commences on the closing date, exceeds 300% of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions after the initial exercise date), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading day and (iii) the warrant holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company, and subject to the Beneficial Ownership Limitation, then we may, within one trading day of the end of such Measurement Period, upon notice (a "Call Notice"), call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered (a "Call") for consideration equal to $0.001 per warrant share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is sent by the Company (such date and time, the "Call Date"). Our right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants.

We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

Outstanding Warrants

Prior to this offering, as of September 30, 2019 we had outstanding warrants to purchase common stock as follows:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A-1 Warrants issued in April 2015 financing	2,175	264.0000	October 2020
(2) Warrants issued in September 2017 financing	8,224	34.9600	March 2023
(3) Warrants issued in June 2018 financing	2,282,000	4.0000	June 2023
(4) Warrants issued in October 2018 financing	624,313	3.1445	October 2023
(5) Warrants issued in May 2019	1,200,000	4.5000	May 2025

Certain Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved preferred stock may enable our board of directors to issue shares of preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue additional preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that holders of common stock will receive dividend payments or payments upon liquidation.

Anti-Takeover Effects of Provisions of Our Charter Documents

Our certificate of incorporation and bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- only the chairman of the board, the chief executive officer, the president or a majority of our board of directors may call special meetings of stockholders, and the business transacted at special meetings of stockholders is limited to the business stated in the notice of such meetings;
- advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders, including certain requirements regarding the form and content of a stockholder's notice;

- our board of directors may designate the terms of and issue new series of preferred stock;
- unless otherwise required by our bylaws, our certificate of incorporation or by law, our board of directors may amend our bylaws without stockholder approval; and
- only our board of directors may fill vacancies on our board of directors.

Anti-Takeover Effects of Provisions of Delaware Law

We are subject to the provisions of Section 203 of the DGCL, or Section 203. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by our board of directors and authorized at a special or annual stockholders meeting, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Limitation of Liability and Indemnification

Our certificate of incorporation provides that our directors shall not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability for breach of the director’s duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, for payment of dividends or approval of stock purchases or redemptions that are prohibited by the DGCL, or for any transaction from which the director derived an improper personal benefit. The inclusion of this provision in our certificate of incorporation may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their duty of care.

Under the DGCL, our directors have a fiduciary duty to us that is not eliminated by this provision of the restated certificate of incorporation and, in appropriate circumstances, equitable remedies such as injunctive or other

forms of non-monetary relief will remain available. This provision also does not affect our directors' responsibilities under any other laws, such as federal securities laws or state or federal environmental laws.

Section 145 of the DGCL empowers a corporation to indemnify its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors or officers of the corporation, if they acted in good faith, in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe that their conduct was unlawful. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. Our restated certificate of incorporation provides that, to the fullest extent permitted by Section 145 of the DGCL, we shall indemnify any person who is or was a director or officer of us, or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against the expenses, liabilities or other matters referred to in or covered by Section 145 of the DGCL. Our amended and restated bylaws provide that we will indemnify any person who was or is a party or threatened to be made a party to any proceeding by reason of the fact that such person is or was a director or officer of us or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise to the fullest extent permitted by the DGCL.

In addition, our bylaws authorize our board of directors to enter into indemnification contracts with each of our officers and directors. We have entered into indemnification contracts with each of our directors and executive officers. The indemnification contracts provide for the indemnification of directors and officers against all expenses, liability, and loss actually reasonably incurred to the fullest extent permitted by our certificate of incorporation, bylaws, and applicable law.

Section 145 of the DGCL also empowers a corporation to purchase insurance for its officers and directors for such liabilities. We maintain liability insurance for our officers and directors.

UNDERWRITING

We have entered into an underwriting agreement dated December 17, 2019 with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters named below, or the representative, and the sole book-running manager of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

Underwriters	Class A Units	Class B Units
Ladenburg Thalmann & Co. Inc.	9,577,504	6,256
Total	9,577,504	6,256

A copy of the underwriting agreement is filed as an exhibit to the registration statement of which this prospectus forms a part.

We have been advised by the underwriters that they propose to offer the units directly to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may sell Class A Units or Class B Units separately to purchasers or may sell a combination of Class A Units and Class B Units to purchasers in any proportion. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $0.05 per share and $0.05 per warrant.

The underwriting agreement provides that subject to the satisfaction or waiver by the representative of the conditions contained in the underwriting agreement, the underwriters are obligated to purchase and pay for all of the units offered by this prospectus.

No action has been taken by us or the underwriters that would permit a public offering of the units, or the shares of common stock, shares of preferred stock, shares of common stock underlying the preferred stock and warrants to purchase common stock included in the units, in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offered hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Class A Unit(1)	Per Class B Unit(1)	Total
Public offering price	$ 0.60	$ 999.60	$12,000,000
Underwriting discount to be paid to the underwriters by us(2)	$ 0.05	$ 49.97	$ 930,000
Proceeds to us (before expenses)	$ 0.55	$ 949.63	$11,070,000

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units, (i) a public offering price per share of common stock of $0.59 and (ii) a public offering price per warrant of $0.01, and (y) in respect of the Class B Units, (i) a public offering price per share of Series B Preferred Stock of $982.94 and (ii) a public offering price per warrant of $16.66.

(2) We have granted a 45 day option to the underwriters to purchase additional shares of common stock and/or warrants to purchase shares of common stock (up to 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series B Preferred Stock) and the number of shares of common stock underlying the warrants sold in the primary offering) at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions, solely to cover overallotments, if any.

We estimate the total expenses payable by us for this offering to be approximately $1.3 million, which amount includes (i) an underwriting discount of $1.0 million ($1.1 million if the underwriters' overallotment option is exercised in full) and (ii) reimbursement of the accountable expenses of the representative equal to $70,000, including the legal fees of the representative being paid by us and (iii) other estimated company expenses of approximately $268,000, which includes legal, accounting and printing costs and various fees associated with the registration and listing of our shares.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement.

Overallotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants to purchase shares of common stock not to exceed 15% of the number of shares of common stock sold in the primary offering (including the number of shares of common stock issuable upon conversion of shares of Series B Preferred Stock, but excluding shares of common stock underlying the warrants issued in this offering and any shares of common stock issued upon any exercise of the underwriters' overallotment option) and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased pursuant to the overallotment option, the underwriters will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "ACHV." On December 16, 2019 the closing price of our common stock was $0.77 per share. We do not intend to apply for listing of the Series B Preferred Stock or the warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors that will be considered in determining the public offering price of the securities:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock, shares of preferred stock or warrants sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

Lock-up Agreements

Our officers and directors, representing approximately 7.18% of our outstanding shares, have agreed with the representative to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the effectiveness of the underwriting agreement, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Other Relationships

Upon completion of this offering, in certain circumstances we have granted the representative a right of first refusal to act as sole bookrunner or exclusive placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares of common stock while this offering is in progress.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriters may be required to make for these liabilities.

LEGAL MATTERS

Certain legal matters relating to the issuance of the securities offered by this prospectus will be passed upon for us by Fenwick & West LLP, Seattle, Washington. Certain legal matters in connection with this offering will be passed upon for the underwriters by Pryor Cashman LLP, New York, New York.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form10-K for the year ended December 31, 2018 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC covering the units we are offering by this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits filed as part of the registration statement for copies of the actual contract, agreement or other document.

We file annual, quarterly and other periodic reports, proxy statements and other information with the Securities and Exchange Commission. You can read our Securities and Exchange Commission filings, including this registration statement, over the Internet at the Securities and Exchange Commission's website at www.sec.gov.

Our Internet address is www.achievelifesciences.com. There we make available free of charge, on or through the investor relations section of our website, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with the Securities and Exchange Commission. The information found on our website is not part of this prospectus and investors should not rely on any such information in deciding whether to invest.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We have elected to incorporate the following documents into this prospectus, together with all exhibits filed therewith or incorporated therein by reference, to the extent not otherwise amended or superseded by the contents of this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 14, 2019;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019, as filed with the SEC on May 15, 2019; June 30, 2019, as filed with the SEC on August 8, 2019; and September 30, 2019, as filed with the SEC on November 6, 2019;
- our Current Reports on Form 8-K filed with the SEC on January 22, 2019; May 15, 2019 (solely with respect to Item 5.07 therein); June 3, 2019; June 7, 2019; and June 11, 2019;
- our Definitive Proxy Statement on Schedule 14A filed with the SEC on March 28, 2019; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on September 27, 1995 under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating such description.

In addition, we incorporate by reference in this prospectus any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (excluding any information furnished and not filed with the SEC) after the date on which the registration statement that includes this prospectus was initially filed with the SEC (including all such documents we may file with the SEC after the date of the initial registration statement) until all offerings under this prospectus are terminated.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for all purposes to the extent that a statement contained in this prospectus or in any other subsequently filed document which is also incorporated or deemed to be incorporated by reference, modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You may request a copy of these filings (other than an exhibit to a filing unless that exhibit is specifically incorporated by reference into that filing) at no cost by writing, telephoning or e-mailing us at the following address, telephone number or e-mail address:

Achieve Life Sciences, Inc.
1040 West Georgia Street, Suite 1030
Vancouver, BC V6E 4H1
Tel: (604) 210-2217
Attn: Sandra Thomson

Copies of these filings are also available through the “Investors” section of our website at www.achievelifesciences.com. For other ways to obtain a copy of these filings, please refer to “Prospectus Summary—Available Information.”

9,577,504 Class A Units consisting of common stock and warrants and
6,256 Class B Units consisting of shares of Series B Preferred Stock and warrants
(and 30,422,496 shares of common stock underlying shares of Series B Preferred Stock and warrants)

PROSPECTUS

Ladenburg Thalmann

December 17, 2019