As filed with the Securities and Exchange Commission on December 2, 2019

Registration No. 333-234530

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 1 to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Achieve Life Sciences, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**2835**	**95-4343413**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

1040 West Georgia, Suite 1030,
Vancouver, British Columbia, V6E 4H1
(604) 210-2217
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Richard Stewart
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Achieve Life Sciences, Inc.
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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered(1)	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee**
Class A Units consisting of:	$7,000,000	$909
(i) Shares of common stock, par value $0.001 per share		
(ii) Warrants to purchase common stock		
Class B Units consisting of:	$15,999,908	$2,077
(i) Shares of Series B Preferred Stock, par value $0.001 per share		
(ii) Shares of common stock issuable on conversion of Series B Preferred Stock(3)		
(iii) Warrants to purchase common stock		
Common stock issuable upon exercise of warrants	$22,999,907	$2,985
Total	$45,999,815	$5,971(4)

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "**Securities Act**") and based on an estimate of the proposed maximum aggregate offering price of all securities being registered.
(2) Includes the price of additional shares of common stock and warrants to purchase shares of common stock that the underwriters have the option to purchase to cover overallotments, if any.
(3) No separate fee is required pursuant to Rule 457(g) under the Securities Act.
(4) Fee of $1,298 paid with prior filing.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated December 2, 2019

4,347,826 Class A Units consisting of common stock and warrants and
16,014 Class B Units consisting of shares of Series B Preferred Stock and warrants
(and 39,130,234 shares of common stock underlying shares of Series B Preferred Stock and warrants)

We are offering 4,347,826 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 an assumed public offering price of $0.92 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 $.

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 will consist of one share of Series B Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock"), convertible into 1,086 shares of common stock and warrants to purchase 1,086 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 an assumed public offering price of $999.12 per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase 1,086 shares of common stock at an exercise price per share of $.

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 additional shares of common stock and/or warrants to purchase 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 November 27, 2019, as reported by The Nasdaq Capital Market, was $0.92 per share. All share and warrant numbers of the securities being offered included in this prospectus are based on an assumed public offering price per share of $0.92 and an assumed conversion price of $0.92 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 13 of this prospectus.

	Per Class A Unit	Per Class B Unit	Total
Public offering price(1)	$	$	$
Underwriting discount(2)(3)	$	$	$
Proceeds, before expenses, to Achieve Life Sciences, Inc.	$	$	$

(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 $ and (ii) a public offering price per warrant of $, and (y) in respect of the Class B Units, (i) a public offering price per share of Series B Preferred Stock of $ and (ii) a public offering price per warrant of $.

(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 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 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 , 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 use e-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 the alpha-4 beta-2, or α4β2, 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 α4β2 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 α4β2 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 2b ORCA-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. Thetrial 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 a 4-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.

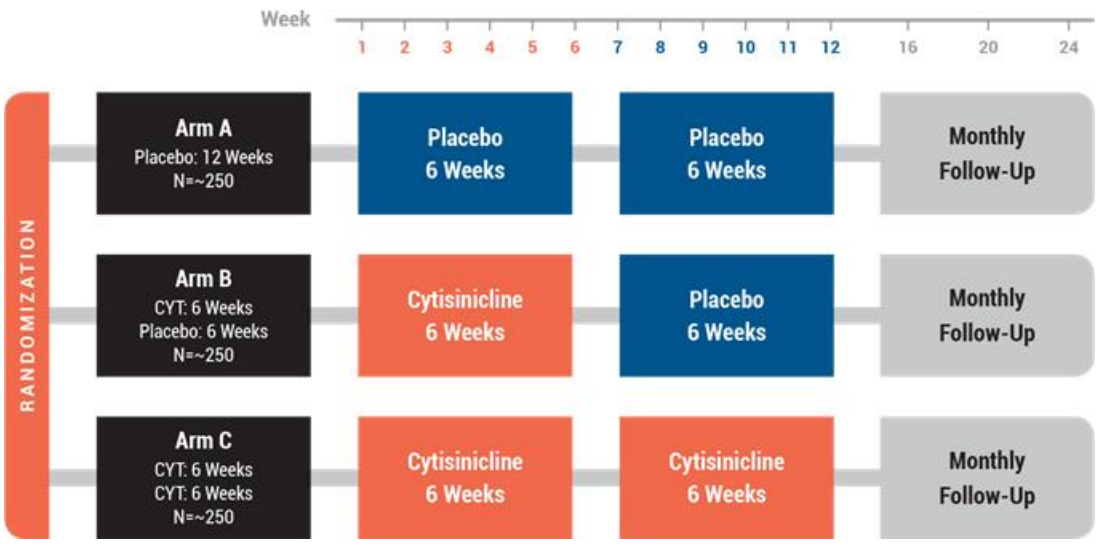
Based on the results of the ORCA-1 trial, we have selected 3.0 mg TID for Phase 3 development. Overall, the 3.0 mg dose administered TID demonstrated the best overall safety and efficacy when compared to other doses and administrations studied in ORCA-1.

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 the ORCA-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 of 6-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 a 4-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 the ORCA-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 4,347,826 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	$0.92
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, Class B Units. Each Class B Unit will consist 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 1,086 and a warrant to purchase 1,086 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	$999.12
Overallotment option	The underwriters have the option to purchase additional shares of common stock, and/or warrants to purchase 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 , 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.
Description of Series B Preferred Stock	Each share of Series B Preferred Stock is convertible at any time at the holder's option into 1,086 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	12,450,590 shares
Shares of Series B Preferred Stock outstanding after this offering	16,014 shares

Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $18.1 million, based on an assumed offering price of $0.92 per Class A Unit (the last reported sale price of our common stock on the Nasdaq Capital Market on November 27, 2019) and $999.12 per Class B Unit, after deducting the estimated 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:

- 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 a period-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 in non-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 proprietary know-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. Forexample, 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 thatof 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. Assuming a public offering price of $8.92 per share, the last reported sale price of our common stock on The Nasdaq Capital Market on November 27, 2019, purchasers of common stock in this offering will experience immediate dilution of $0.15 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 $. 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 $18.1 million, based on an assumed offering price of $0.92 per Class A Unit and $999.12 per Class B Unit, after deducting the estimated 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 $20.8 million, after deducting the estimated 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.

A $1.00 increase (decrease) in the assumed public offering price of the Class A Units (assuming no Class B Units are sold) would increase (decrease) the net proceeds to us from this offering by $4.0 million, assuming the number of Class A Units offered by us remains the same and after deducting the estimated underwriting discounts and commissions. Similarly, each aggregate increase (decrease) of one million Class A Units (assuming no Class B Units are sold) would increase (decrease) the net proceeds to us from this offering by approximately $0.8 million, assuming that the assumed public offering price of Class A Units remains the same and after deducting the estimated underwriting discounts and commissions.

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 November 27, 2019 was $0.92 per share. As of November 27, 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 4,347,826 Class A Units and 16,014 Class B Units in this offering, based on an assumed offering price of $0.92 per Class A Unit and $999.12 per Class B Unit, after deducting the estimated 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	$ 25,432
Stockholders' equity (deficit)		
Preferred Stock, par value $0.001 per share; 5,000,000 shares authorized; no shares issued and outstanding 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 as of September 30, 2019	19	23
Additional paid-in capital	50,628	68,681
Accumulated deficit	(42,510)	(42,510)
Accumulated other comprehensive income	4	4
Total stockholders' equity	8,141	26,198
Total capitalization	8,141	26,198

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:

- 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 4,347,826 Class A Units and 16,014 Class B Units in this offering, based on an assumed offering price of $0.92 per Class A Unit and $999.12 per Class B Unit, after deducting the estimated 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 1,086 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 $23.0 million, or $0.77 per share of common stock. This represents an immediate increase in the net tangible book value of $0.16 per share to our existing stockholders and an immediate dilution in net tangible book value of $0.15 per share to the investor in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share of common stock		$ 0.92
Net tangible book value per share as of September 30, 2019	$ 0.61	
Increase in net tangible book value per share attributable to the offering	0.16	
As adjusted net tangible book value per share after giving effect to the offering		0.77
Dilution in net tangible book value per share to new investor		$ 0.15

The dilution information set forth in the table above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

A $1.00 increase (decrease) in the assumed public offering price of the Class A Units (assuming no Class B Units are sold) would increase (decrease) our as adjusted net tangible book value per share after this offering by $0.67, assuming the number of Class A Units offered by us remains the same and after deducting the estimated underwriting discounts and commissions. Similarly, each aggregate increase (decrease) of one million Class A Units (assuming no Class B Units are sold) would increase (decrease) the dilution to new investors by $0.00 per share, assuming that the assumed public offering price of Class A Units remains the same and after deducting the estimated underwriting discounts and commissions.

The table above excludes:

- 21,739,030 shares of our 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 asof 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 4,347,826 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 $, together with the shares of common stock underlying such warrants, at an assumed public offering price of $0.92 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%), 16,014 Class B Units. Each Class B Unit will consist of one share of Series B Preferred Stock, par value $0.001 per share, convertible into 1,086 shares of common stock and a warrant to purchase 1,086 shares of our common stock at an exercise price per share of $, together with the shares of common stock underlying such shares of Series B Preferred Stock and warrants, at an assumed public offering price of $999.12 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 isAmerican 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 an as-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 1,086 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 beAmerican 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 a warrant to purchase one share of our common stock at a price equal to $ 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 and the number of shares issuable upon exercise of the warrants is 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 , 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.		
Total		

A copy of the underwriting agreement will be 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 $ per share and $ 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			
Underwriting discount to be paid to the underwriters by us(2)			
Proceeds to us (before expenses)			

(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 $ and (ii) a public offering price per warrant of $, and (y) in respect of the Class B Units, (i) a public offering price per share of Series B Preferred Stock of $ and (ii) a public offering price per warrant of $.

(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 $1.8 million, which amount includes (i) an assumed underwriting discount of $1.6 million ($1.9 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 $272,000, 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 November 27, 2019 the closing price of our common stock was $0.92 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 isAmerican 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 Form 10-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.”

4,347,826 Class A Units consisting of common stock and warrants and
16,014 Class B Units consisting of shares of Series B Preferred Stock and warrants
(and 39,130,234 shares of common stock underlying shares of Series B Preferred Stock and warrants)

PROSPECTUS

Ladenburg Thalmann

, 2019

PART II

Information Not Required in Prospectus

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the fees and expenses, other than placement agent fees and expenses, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

Item	Amount to be paid
SEC registration fee	$ 5,971
FINRA filing fee	6,500
Printing expenses	20,000
Legal fees and expenses	150,000
Accounting fees and expenses	40,000
Transfer Agent fees and expenses	10,000
Miscellaneous expenses	110,000
Total	342,471

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Our Second Amended and Restated Certificate of Incorporation, as amended and as may be further amended and in effect from time to time, which we refer to as the 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 General Corporation Law of the State of Delaware, as amended, which we refer to as the DGCL, or for any transaction from which the director derived an improper personal benefit. 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. The 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, we have entered into agreements with each of our directors and officers under which, among other things, we have agreed to indemnify the director or officer against expenses incurred in any proceeding, including any action by us, in which the director or officer was, is or is threatened to be made a party or a participant by reason of his or her status as a present or former director, officer, employee or agent of us or, at our request, any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. At present, there is no pending litigation or proceeding involving any director or officer as to which indemnification will be required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

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.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

On October 1, 2018, we issued warrants to purchase an aggregate of 894,626 shares of Common Stock at an exercise price of $3.1445 per share to purchasers participating in a concurrent registered direct offering. The warrants were offered and issued to the purchasers in reliance upon the exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act.

On May 30, 2019, we issued a warrant to purchase an aggregate of 1,200,000 shares of Common Stock at an exercise price of $4.50 per share to Armistice Capital Master Fund, Ltd. (the "Holder"), as an inducement for the Holder to exercise certain outstanding warrants. The warrant was offered and issued to the Holder in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	Form of Underwriting Agreement					X
2.1†	Agreement and Plan of Merger and Reorganization, dated as of January 5, 2017, by and among OncoGenex Pharmaceuticals, Inc., Ash Acquisition Sub, Inc., Ash Acquisition Sub 2, Inc. and Achieve Life Science, Inc.	8-K	033-80623	2.1	January 5, 2017	
2.2	Amendment No. 2 to Agreement and Plan of Merger and Reorganization, dated July 19, 2017, by and among Achieve Life Sciences, Inc., Ash Acquisition Sub, Inc., Ash Acquisition Sub 2, Inc., and Achieve Life Science, Inc.	8-K	33-80623	10.1	July 19, 2017	
3.1	Second Amended and Restated Certificate of Incorporation filed on May 24, 2013	8-K	033-80623	3.1	May 29, 2013	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed on May 21, 2015	8-K	033-80623	3.1	May 22, 2015	
3.3	Certificate of Amendment (Reverse Stock Split) to Second Amended and Restated Certificate of Incorporation filed on August 1, 2017	8-K	033-80623	3.1	August 2, 2017	
3.4	Certificate of Amendment (Name Change) to Second Amended and Restated Certificate of Incorporation filed on August 1, 2017	8-K	033-80623	3.2	August 2, 2017	
3.5	Certificate of Amendment (Elimination of Cumulative Voting) to Second Amended and Restated Certificate of Incorporation filed on October 31, 2017	8-K	033-80623	3.1	November 1, 2017	
3.6	Certificate of Amendment (Reverse Stock Split) to Second Amended and Restated Certificate of Incorporation filed on May 22, 2018	8-K	033-80623	3.1	May 23, 2018	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.7	Certificate of Amendment (Increase in Authorized Shares) to Second Amended and Restated Certificate of Incorporation filed on May 22, 2018	8-K	033-80623	3.2	May 23, 2018	
3.8	Certificate of Designation of Preferences, Rights and Limitations, with respect to the Series A Convertible Preferred Stock, filed June 18, 2018	8-K	033-80623	3.1	June 20, 2018	
3.9	Sixth Amended and Restated Bylaws	8-K	033-80623	3.1	January 5, 2017	
3.10	Amendment to Sixth Amended and Restated Bylaws	10-Q	033-80623	3.1	November 7, 2018	
3.11	Form of Certificate of Designation of Series A Preferred Stock	S-1/A	333-224840	3.9	June 12, 2018	
3.12**	Form of Certificate of Designation of Series B Preferred Stock					
4.1	Specimen Certificate of Common Stock	10-Q	000-21243	4.1	November 10, 2008	
4.2	Form of Series A-1 Warrant	8-K	033-80623	4.1	April 30, 2015	
4.3	Form of Pre-Funded Series B Warrant	8-K	033-80623	4.2	June 27, 2014	
4.4	Form of Warrant (LPC)	8-K	033-80623	4.1	September 14, 2017	
4.5	Form of Common Stock Purchase Warrant (June 2018 Offering)	8-K	033-80623	4.1	June 20, 2018	
4.6	Form of Preferred Stock Certificate	8-K	033-80623	4.2	June 20, 2018	
4.7	Form of Warrant (October 2018 Private Placement)	8-K	033-80623	4.1	October 1, 2018	
4.8	Form of Warrant (May 2019)	8-K	033-80623	4.1	June 3, 2019	
4.9**	Form of Warrant Offered Hereby					
4.10**	Form of Series B Preferred Stock Certificate					
5.1	Opinion of Fenwick & West LLP					X
10.1	Sonus Pharmaceuticals, Inc. 2007 Performance Incentive Plan (the "2007 Plan")	DEF 14A	000-21243	Appendix A	April 3, 2007	
10.2	Form of Sonus Pharmaceuticals, Inc. Stock Option Agreement (pertaining to the 2007 Plan)	10-Q	000-21243	10.1	November 9, 2007	
10.3	OncoGenex Technologies Inc. Amended and Restated Stock Option Plan	F-1	333-139293	10.1	December 13, 2006	
10.4	Form of OncoGenex Pharmaceuticals, Inc. 2010 Stock Option Agreement	8-K	033-80623	10.1	June 14, 2010	
10.5	Form of OncoGenex Pharmaceuticals, Inc. 2010 Restricted Stock Unit Agreement	10-Q	033-80623	10.2	November 3, 2011	
10.6	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated	DEF 14A	033-80623	Appendix A	April 16, 2015	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.7a	Achieve Life Sciences 2017 Equity Incentive Plan	DEF 14A	033-80623	Appendix A	September 21, 2017	
10.7b	Form of Achieve Life Sciences Stock Option Agreement	10-K	033-80623	10.7b	March 1, 2018	
10.7c	Form of Achieve Life Sciences Restricted Stock Unit Agreement	10-K	033-80623	10.7c	March 1, 2018	
10.8	Achieve Life Sciences 2017 Employee Stock Purchase Plan	DEF 14A	033-80623	Appendix B	September 21, 2017	
10.9	Achieve Life Sciences 2018 Equity Incentive Plan, and forms of award agreements thereunder	10-Q	033-80623	10.1	November 7, 2018	
10.10	Form of Indemnification Agreement for Officers and Directors of the Company	S-1	333-234530	10.10	November 6, 2019	
10.11	Form of Indemnification Agreement between OncoGenex Technologies Inc. and Cindy Jacobs	F-1	333-139293	10.7	December 13, 2006	
10.12	Employment Agreement between the Company and Cindy Jacobs dated as of November 3, 2009	10-Q	033-80623	10.27	November 5, 2009	
10.13	Employment Agreement between OncoGenex Pharmaceuticals, Inc. and John Bencich	10-Q	033-80623	10.1	November 10, 2016	
10.14	Employment Agreement between the Company and Richard Stewart, executed May 22, 2018	8-K	033-80623	10.1	May 23, 2018	
10.15	Employment Agreement between the Company and Anthony Clarke, executed May 22, 2018	8-K	033-80623	10.2	May 23, 2018	
10.16#	Exclusive License Agreement, by and between Sopharma Joint Stock Company and Extab Corporation, dated May 26, 2009	S-4/A	333-216961	10.21	May 3, 2017	
10.17#	Variation of Contract, by and between Sopharma AD and Extab Corporation, dated May 14, 2015	S-4/A	333-216961	10.22	May 3, 2017	
10.18#	Commercial Agreement on Supply of Pharmaceutical Products, by and between Sopharma AD and Extab Corporation, dated February 1, 2010	S-4/A	333-216961	10.23	May 3, 2017	
10.19#	Variation of Contract, by and between Sopharma AD and Extab Corporation, dated May 14, 2015	S-4/A	333-216961	10.24	May 3, 2017	
10.20#	Technical and Quality Agreement, by and between Sopharma AD and Extab Corporation, dated May 14, 2015	S-4/A	333-216961	10.25	May 3, 2017	
10.21#	License of Technology, by and between University of Bristol and Achieve Life Science, Inc., dated July 13, 2016	S-4/A	333-216961	10.27	May 3, 2017	
10.22##	Amendment to University of Bristol License Agreement, dated January 22, 2018, by and between Achieve Life Science, Inc., and the University of Bristol	10-Q/A	033-80623	10.1	May 23, 2018	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.23	Lease by and between 520 Pike Street, Inc. and Achieve Life Sciences, Inc., dated December 1, 2017	10-K	033-80623	10.20	March 1, 2018	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.24	Office Lease by and between 0846869 B.C. Ltd. and Achieve Life Sciences Technologies Inc., commencing February 1, 2019	10-K	033-80623	10.25	March 14, 2019	
10.25	Purchase Agreement, by and between Achieve Life Sciences, Inc. and Lincoln Park Capital Fund, LLC. dated as of September 14, 2017	8-K	033-80623	10.1	September 14, 2017	
10.26##	Amended and Restated Supply Agreement, dated July 28, 2017, by and between Achieve Life Science, Inc., and Sopharma AD	10-Q	033-80623	10.1	November 9, 2017	
10.27	Warrant Exercise Agreement by and between Armistice Capital Master Fund, Ltd. and Achieve Life Sciences, Inc., dated May 30, 2019	8-K	033-80623	10.1	June 3, 2019	
10.28	At The Market Offering Agreement by and between H.C. Wainwright & Co., LLC and Achieve Life Sciences, Inc., dated June 7, 2019	8-K	033-80623	1.1	June 7, 2019	
21.1	Subsidiaries of the Registrant	10-K	033-80623	21.1	March 1, 2018	
23.1	Consent of PricewaterhouseCoopers LLP					X
23.2	Consent of Fenwick & West LLP (included in Exhibit 5.1)					X
24.1	Power of Attorney	S-1	333- 234530	24.1	November 6, 2019	

** To be filed by amendment.

† Schedules and similar attachments to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish supplementally a copy of any omitted schedule or similar attachment to the SEC upon request.

Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to a Confidential Treatment Order granted under Rule 406 promulgated under the Securities Act of 1933, as amended.

Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to a Confidential Treatment Order granted under Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

ITEM 17. UNDERTAKINGS

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

(a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) For purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Vancouver, British Columbia, Canada, on December 2, 2019.

ACHIEVE LIFE SCIENCES, INC.

By: /s/ Richard Stewart
Richard Stewart
Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and as of the dates indicated.

Signature	Title	Date
/s/ Richard Stewart Richard Stewart	Chief Executive Officer, Chairman and Director (Principal Executive Officer)	December 2 , 2019
/s/ John Bencich John Bencich	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 2 , 2019
* Scott Cormack	Director	December 2, 2019
* Anthony Clarke	Director	December 2 , 2019
* Martin Mattingly	Director	December 2, 2019
* H. Stewart Parker	Director	December 2, 2019
* Jay Moyes	Director	December 2 , 2019
* Donald Joseph	Director	December 2 , 2019

* By: /s/ John Bencich
John Bencich
Attorney-in-Fact

Exhibit 1.1

[ ] SHARES OF COMMON STOCK,
[ ] SHARES OF SERIES B CONVERTIBLE PREFERRED STOCK
(CONVERTIBLE INTO [ ] SHARES OF COMMON STOCK), AND
[ ] WARRANTS (EXERCISABLE FOR [ ] SHARES OF COMMON STOCK)

OF

ACHIEVE LIFE SCIENCES, INC.

UNDERWRITING AGREEMENT

[ ], 2019

Ladenburg Thalmann & Co. Inc.
As the Representative of the
Several underwriters, if any, named in Schedule I hereto
999 Vanderbilt Beach Road, Suite 200
Naples, Florida 34108

Ladies and Gentlemen:

The undersigned, Achieve Life Sciences, Inc., a Delaware corporation (collectively with its subsidiaries, including, without limitation, all entities disclosed or described in the Registration Statement as being subsidiaries of Achieve Life Sciences, Inc., the "Company"), hereby confirms its agreement (this "Agreement") with the several underwriters (such underwriters, including the Representative (as defined below), the "Underwriters" and each an "Underwriter") named in Schedule I hereto for which Ladenburg Thalmann & Co. Inc. is acting as representative to the several Underwriters (the "Representative" and if there are no Underwriters other than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Public Securities as soon as the Representative deems it advisable to do so. The Public Securities are to be initially offered to the public at the public offering price set forth in the Prospectus. The Representative may from time to time thereafter change the public offering price and other selling terms.

It is further understood that you will act as the Representative for the Underwriters in the offering and sale of the Closing Securities and, if any, the Option Securities in accordance with this Agreement.

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, (a) capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Certificate of Designation (as defined herein) and (b) the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Certificate of Designation" means the Certificate of Designation to be filed prior to the Closing by the Company with the Secretary of State of Delaware, in the form of Exhibit A attached hereto.

"Closing" means the closing of the purchase and sale of the Closing Securities pursuant to Section 2.1.

"Closing Date" means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters' obligations to pay the Closing Purchase Price and (ii) the Company's obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 12:00 p.m. (New York City time) on the second Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

"Closing Preferred Shares" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Closing Securities" shall have the meaning ascribed to such term in Section 2.1(a)(iii).

"Closing Shares" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Closing Warrants" shall have the meaning ascribed to such term in Section 2.1(a)(iii).

"Combined Preferred Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Combined Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company Auditor" means PricewaterhouseCoopers LLP , with offices located at 250 Howe Street, Suite 1400, Vancouver, British Columbia V6C 3S7.

"Company Counsel" means Fenwick & West LLP, with offices located at 1191 2nd Ave, 10th Floor, Seattle, Washington 98101.

"Conversion Price" shall have the meaning ascribed to such term in the Certificate of Designation.

"Conversion Shares" shall have the meaning ascribed to such term in the Certificate of Designation.

"Effective Date" shall have the meaning ascribed to such term in Section 3.1(f).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Execution Date" shall mean the date on which the parties execute and enter into this Agreement.

"Exempt Issuance" means the issuance of (a) shares of Common Stock, options, restricted stock units or other equity awards to employees, officers or directors of the Company pursuant to any stock or option plan or other equity award plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such

purpose, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within 90 days following the Closing Date, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, and (d) securities issued by the Company with the prior written consent of the Representative.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FINRA" means the Financial Industry Regulatory Authority.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(i).

"Indebtedness" means (a) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (b) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (c) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP.

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Lock-Up Agreements" means the lock-up agreements that are delivered on the date hereof by each of the Company's officers and directors and each holder of Common Stock that beneficially owns more than 5% of the Company's issued and outstanding Common Stock, in the form of Exhibit C attached hereto.

"Material Adverse Effect" means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document; provided that a change in the market price or trading

volume of the Common Stock alone shall not be deemed, in and of itself, to constitute a Material Adverse Effect and adverse effects resulting solely from or relating solely to the following shall be not be taken into account in determining whether there has been a Material Adverse Effect, except, in the case of clauses (a), (b) and (d) below, to the extent the impact of the event described therein has an adverse effect on the Company taken as a whole that is materially disproportionate to the Company taken as a whole compared to other companies operating in the same industry: (a) general economic conditions, or conditions in financial, banking or securities markets; (b) general conditions in the industry or any industry sector in which the Company operates or participates; (c) any natural disaster or any national or international political or social conditions or any act of terrorism, sabotage, military action or war or any escalation or worsening thereof or (d) any changes in applicable laws or governmental regulations or the interpretation thereof.

"Offering" shall have the meaning ascribed to such term in Section 2.1(c).

"Option Closing Date" shall have the meaning ascribed to such term in Section 2.2(c).

"Option Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.2(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Option Securities" shall have the meaning ascribed to such term in Section 2.2(a).

"Option Shares" shall have the meaning ascribed to such term in Section 2.2(a)(i).

"Option Warrants" shall have the meaning ascribed to such term in Section 2.2(a).

"Over-Allotment Option" shall have the meaning ascribed to such term in Section 2.2.

"PC" means Pryor Cashman LLP, with offices located at 7 Times Square, New York, New York 10036.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Preferred Stock" means up to [ ] shares of the Company's Series B Convertible Preferred Stock issued or issuable pursuant to Section 2.1(a)(i) and having the rights, preferences and privileges set forth in the Certificate of Designation.

"Preliminary Prospectus" means, if any, any preliminary prospectus relating to the Securities included in the Registration Statement or filed with the Commission pursuant to Rule 424(b).

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition),

whether commenced or threatened.

"Prospectus" means the final prospectus filed for the Registration Statement.

"Prospectus Supplement" means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

"Public Securities" means, collectively, the Closing Securities and, if any, the Option Securities.

"Registration Statement" means, collectively, the various parts of the registration statement prepared by the Company on Form S-1 (File No. 333-234530) with respect to the Securities, each as amended as of the date hereof, including the Prospectus and Prospectus Supplement, if any, the Preliminary Prospectus, if any, and all exhibits filed with or incorporated by reference into such registration statement, and includes any Rule 462(b) Registration Statement.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Required Minimum" means, as of any date, the maximum aggregate number of shares of Common Stock then issued or potentially issuable in the future pursuant to the Transaction Documents, including any Underlying Shares issuable upon exercise in full of all Warrants or conversion in full of all shares of Preferred Stock, ignoring any conversion or exercise limits set forth therein.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 462(b) Registration Statement" means any registration statement prepared by the Company registering additional Closing Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(i).

"Securities" means the Closing Securities, the Option Securities and the Underlying Shares.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Share Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Shares" means, collectively, the shares of Common Stock delivered to the

Underwriters in accordance with Section 2.1(a)(ii) and Section 2.2(a).

"Stated Value" means $[ ] per share of Preferred Stock.

"Subsidiary" means any subsidiary of the Company.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, the Certificate of Designation, the Warrants, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means American Stock Transfer & Trust Company, with offices located at 6201 15 th Avenue, Brooklyn, New York 11219, and any successor transfer agent of the Company.

"Underlying Shares" means, collectively, the Conversion Shares and the Warrant Shares.

"Warrant Agency Agreement" means the warrant agency agreement dated on or about the date hereof, between the Company and the Transfer Agent, pursuant to which the Transfer Agent will act as warrant agent for the Warrants.

"Warrant Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants.

"Warrants" means, collectively, the Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(iii) and Section 2.2(a), which warrants shall be exercisable immediately and have a term of exercise equal to five (5) years, in the form of Exhibit B attached hereto.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell in the aggregate [ ] shares of Common Stock, [ ] shares of Preferred Stock, and [ ] Warrants, and each Underwriter agrees to purchase, severally and not jointly, at

the Closing, the following securities of the Company:

(i) the number of shares of Preferred Stock (the "Closing Preferred Shares") set forth opposite the name of such Underwriter on Schedule I hereof;

(ii) the number of shares of Common Stock (the "Closing Shares") set forth opposite the name of such Underwriter on Schedule I hereof; and

(iii) Warrants to purchase up to [ ]% of the sum of the number of Closing Shares set forth opposite the name of such Underwriter on Schedule I hereof plus the aggregate number of Conversion Shares underlying the Closing Preferred Shares set forth opposite the name of such Underwriter on Schedule I hereof (the "Closing Warrants" and, collectively with the Closing Shares and the Closing Preferred Shares, the "Closing Securities"), which Warrants shall have an exercise price of $[ ], subject to adjustment as provided therein.

(b) The aggregate purchase price for the Closing Securities shall equal the amount set forth opposite the name of such Underwriter on Schedule I hereto (the "Closing Purchase Price"). The combined purchase price for one Share and a Warrant to purchase one Warrant Share shall be $[ ] (the "Combined Purchase Price") which shall be allocated as $[ ] per Share (the "Share Purchase Price") and $[ ] per Warrant (the "Warrant Purchase Price"). The combined purchase price for one Closing Preferred Share and Warrants to purchase [ ] Warrant Shares shall be $[ ] (the "Combined Preferred Purchase Price") which shall be allocated as $[ ] per Preferred Share and $[ ] per Warrant or $[ ] for Warrants to purchase [ ] Warrant Shares. Notwithstanding the foregoing, the combined purchase price for one Share and a Warrant to purchase one Warrant Share sold to certain investors set forth on Exhibit B of the Investment Bank Agreement shall be $[ ] (the "Reduced Combined Purchase Price") which shall be allocated as $[ ] per Share (the "Reduced Share Purchase Price") and $[ ] per Warrant (the "Reduced Warrant Purchase Price"). The combined purchase price for one Closing Preferred Share and Warrants to purchase [ ] Warrant Shares sold to certain investors set forth on Exhibit B of the Investment Bank Agreement shall be $[ ] (the "Reduced Combined Preferred Purchase Price") which shall be allocated as $[ ] per Preferred Share and $[ ] per Warrant or $[ ] for Warrants to purchase [ ] Warrant Shares.

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of PC or such other location as the Company and Representative shall mutually agree. The Public Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

(d) The Company acknowledges and agrees that, with respect to any Notice(s) of Conversion (as defined in the Certificate of Designation) delivered by a Holder (as

defined in the Certificate of Designation) on or prior to 10:00 a.m. (New York City time) on the Closing Date, which Notice(s) of Conversion may be delivered at any time after the time of execution of this Agreement, the Company shall deliver the Conversion Shares (as defined in the Certificate of Designation) subject to such notice(s) to the Holder by 4:00 p.m. (New York City t ime) on the Closing Date. The Company acknowledges and agrees that the Holders are third-party beneficiaries of this covenant of the Company.

2.2 Over-Allotment Option.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Closing Securities, the Representative is hereby granted an option (the "Over-Allotment Option") to purchase, in the aggregate, up to [ ] shares of Common Stock (the "Option Shares") and Warrants to purchase up to [ ] shares of Common Stock (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities") which may be purchased in any combination of Option Shares and/or Option Warrants at the Share Purchase Price and/or Warrant Purchase Price, respectively.

(b) In connection with an exercise of the Over-Allotment Option, (a) the purchase price to be paid for the Option Shares is equal to the product of the Share Purchase Price multiplied by the number of Option Shares to be purchased and (b) the purchase price to be paid for the Option Warrants is equal to the product of the Warrant Purchase Price multiplied by the number of Option Warrants (the aggregate purchase price to be paid on an Option Closing Date, the "Option Closing Purchase Price").

(c) The Over-Allotment Option granted pursuant to this Section 2.2 may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within forty-five (45) days after the Execution Date. An Underwriter will not be under any obligation to purchase any Option Securities prior to the exercise of the Over-Allotment Option by the Representative. The Over-Allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Securities (each, an "Option Closing Date"), which will not be later than two (2) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of PC or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Over-Allotment Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice. The Representative may cancel the Over-Allotment Option at any time prior to the expiration of the Over-Allotment Option by written notice to the Company.

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(i) At the Closing Date, the Closing Shares and, as to each Option Closing Date, if any, the applicable Option Shares, which shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(ii) At the Closing Date, the Closing Preferred Shares, which shares shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(iii) At the Closing Date, the Closing Warrants and, as to each Option Closing Date, if any, the applicable Option Warrants, which shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(iv) At the Closing Date, evidence of the filing and acceptance of the Certificate of Designation from the Secretary of State of Delaware;

(v) At the Closing Date, the Warrant Agency Agreement duly executed by the parties thereto;

(vi) At the Closing Date, the Transfer Agent is duly appointed as the transfer agent and conversion agent for the Preferred Stock;

(vii) At the Closing Date, a legal opinion of Company Counsel addressed to the Underwriters, including, without limitation, a negative assurance paragraph, in the form and substance reasonably satisfactory to the Representative, and as to each Option Closing Date, if any, a bring-down opinion, including a negative assurance paragraph, from Company Counsel in form and substance reasonably satisfactory to the Representative;

(viii) Contemporaneously herewith, a cold comfort letter, addressed to the Underwriters and in form and substance reasonably satisfactory in all respects to the Representative from the Company Auditor dated, respectively, as of the date of this Agreement and a bring-down letter dated as of the Closing Date and each Option Closing Date, if any;

(ix) On the Closing Date and on each Option Closing Date, the duly executed and delivered Officer's Certificate, in the form and substance reasonably satisfactory to the Representative;

(x) On the Closing Date and on each Option Closing Date, the duly executed and delivered Secretary's Certificate, in the form and substance reasonably satisfactory to the Representative; and

(xi) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2.4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing and each Option Closing Date are subject to the following conditions being met:

(i) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the date in question shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(iv) the Registration Statement shall be effective on the date of this Agreement and at each of the Closing Date and each Option Closing Date, if any, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(v) by the Execution Date, if required by FINRA, the Underwriters shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement;

(vi) the Closing Shares, the Option Shares and the Underlying Shares have been approved for listing on the Trading Market; and

(vii) prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement and Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto shall contain any

untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date and as of each Option Closing Date, if any, as follows:

(a) Subsidiaries. All of the direct and indirect Subsidiaries of the Company are set forth in the SEC Reports. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in a Material Adverse Effect and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement, the Warrant Agency Agreement and each of the other Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement, the Warrant Agency Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement, the Warrant Agency Agreement and each other Transaction Document to which the Company is a party has been (or upon delivery or filing will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid

and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the Warrant Agency Agreement, the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents and the Warrant Agency Agreement, other than: (i) the filing with the Commission of the Prospectus, (ii) the filing of the Certificate of Designation with the Delaware Secretary of State; (iii) the application to the Trading Market for the listing of the Shares and the Underlying Shares for trading thereon, (iv) the notices, forms and authorizations of The Depository Trust & Clearing Corporation related to the account and transfer of the Warrants and (v) such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Prospectus or Prospectuses, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The Registration Statement has been declared effective by the Commission on [ ], 20[ ] (the "Effective Date"). The Company has advised the Representative of all further

information (financial and other) with respect to the Company required to be set forth therein in the Registration Statement and Prospectus. Any reference in this Agreement to the Registration Statement, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein; and any reference in this Agreement to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, the Prospectus or any Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Prospectus or any Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is "contained," "included," "described," "referenced," "set forth" or "stated" in the Registration Statement, the Prospectus or any Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Prospectus or any Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Prospectus or any Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company's knowledge, is threatened by the Commission. For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act. The Company will not, without the prior consent of the Representative, prepare, use or refer to, any free writing prospectus.

(g) Issuance of Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents and the Warrant Agency Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Underlying Shares, when issued in accordance with the terms of the Transaction Documents and the Warrant Agency Agreement, will be validly issued, fully paid and nonassessable, and free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock a number of shares of Common Stock for issuance of the Underlying Shares at least equal to the Required Minimum and the Option Shares issuable pursuant to the Over-Allotment Option on the date hereof. The Securities are not subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement.

(h) Capitalization. The capitalization of the Company is as set forth in the SEC Reports as of the dates provided in such SEC Reports. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options and settlement of restricted stock units under the Company's equity plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by

the Transaction Documents. Except as a result of the purchase and sale of the Securities and as described in the Registration Statement and Prospectus, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Underwriters) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the Registration Statement and the Prospectus. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(i) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and any Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes

thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The agreements and documents described in the Registration Statement, the Preliminary Prospectus, the Prospectus, any Prospectus Supplement and the SEC Reports conform to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Prospectus, any Prospectus Supplement or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is bound or affected and (i) that is referred to in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the best of the Company's knowledge, any other party is in default thereunder and, to the best of the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the best of the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a material violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock, (v) the Company has not issued any

equity securities to any officer, director or Affiliate, except pursuant to existing Company equity plans and (vi) no officer or director of the Company has resigned from any position with the Company. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made. Unless otherwise disclosed in an SEC Report filed prior to the date hereof, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(k) Litigation. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents, the Warrant Agency Agreement or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor, to the Company's knowledge, any current director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or, to the Company's knowledge, any current director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(l) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state,

local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(m) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (each, a "Material Permit"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. The disclosures in the Registration Statement concerning the effects of Federal, State, local and all foreign regulation on the Company's business as currently contemplated are correct in all material respects.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to, or have valid and marketable rights to lease or otherwise use, all real property and all personal property that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance, except where the failure to be in compliance could not reasonably be expected to have a Material Adverse Effect.

(p) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as described in the SEC Reports as necessary or required

for use in connection with their respective businesses and which the failure to do so could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions With Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from, any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any equity incentive plan of the Company.

(s) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in material compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit

preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(u) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) Registration Rights. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the SEC Reports, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for

electronic transfer through the Depository Trust Company or another established clearing corporation.

(x) Application of Takeover Protections. The Company and the Board of Directors or a duly authorized committee thereof have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable as a result of the Underwriters and the Company fulfilling their obligations or exercising their rights under the Transaction Documents and the Warrant Agency Agreement.

(y) Disclosure; 10b-5. The Registration Statement contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations under the Securities Act and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Preliminary Prospectus, the Prospectus and any Prospectus Supplement, each as of its respective date, comply in all material respects with the Securities Act and the Exchange Act and the applicable rules and regulations. Each of the Preliminary Prospectus, the Prospectus and any Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to the SEC Reports incorporated by reference in the Prospectus), in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Prospectus or any Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required.

(z) No Integrated Offering. Neither the Company, nor, to the Company's knowledge, any of its Affiliates or any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees,

assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the FCPA.

(dd) Accountants. To the knowledge and belief of the Company, the Company Auditor (i) is an independent registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2019. Except as set forth in the SEC Reports, the Company Auditor has not, during the periods covered by the financial statements included in the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(ee) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical

hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ff) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

(gg) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon the Representative's request.

(hh) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(ii) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in material compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(jj) D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires completed by each of the Company's directors and officers immediately prior to the Offering as well as in the Lock-Up Agreement provided to the Underwriters is true and correct in all respects and the Company has not become aware of

any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

(kk) FINRA Affiliation. To the Company's knowledge, no officer, director or any beneficial owner of 5% or more of the Company's unregistered securities has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA) that is participating in the Offering.

(ll) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Representative or PC shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(mm) Board of Directors. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Prospectus and the Prospectus Supplement, as amended or supplemented, in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Prospectus, the Prospectus Supplement, the Registration Statement, any Permitted Free Writing Prospectus, and copies of the documents incorporated by reference therein. The Company shall not file any such amendment or supplement to which the Representative shall reasonably object in writing.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use its reasonable best efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the Company or counsel for the Underwriters, the Prospectus, as then amended or

supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Filing of Final Prospectus. The Company will file the final Prospectus (in form and substance reasonably satisfactory to the Representative) with the Commission pursuant to the requirements of Rule 424.

(c) Exchange Act Registration. For a period of three years from the Execution Date, the Company will use its best efforts to maintain the registration of the Common Stock under the Exchange Act. The Company will not deregister the Common Stock under the Exchange Act without the prior written consent of the Representative.

(d) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is herein referred to as a **"**Permitted Free Writing Prospectus." The Company represents that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus" as defined in rule and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, if requested, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, deliver to the Representatives two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use its reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus until the later of nine (9) months from the Execution Date and the date on which the Warrants are no longer outstanding, and will notify the Underwriters and holders of the Warrants promptly: (i) of the effectiveness of the Registration Statement and any amendment thereto; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the

Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Expenses.

(a) General Expenses Related to the Offering. The Company hereby agrees to pay on each of the Closing Date and each Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering (including the Option Securities) with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; all fees and expenses relating to the listing of such Closing Shares, Option Shares and Underlying Shares on the Trading Market and such other stock exchanges as the Company and the Representative together determine; (c) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the "blue sky" securities laws of such states and other foreign jurisdictions as the Representative may reasonably designate; (d) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (e) the costs and expenses of the Company's public relations firm; (f) the costs of preparing, printing and delivering the Securities; (g) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company), including, without limitation, fees and expenses pursuant to the Warrant Agency Agreement and appointment of the Transfer Agent as the transfer agent and warrant for the Preferred Stock; (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (i) the fees and expenses of the Company's accountants; (j) the fees and expenses of the Company's legal counsel and other agents and representatives; (k) the Underwriters' costs of mailing prospectuses to prospective investors; (l) the costs associated wit h advertising the Offering in the national editions of the Wall Street Journal and New York Times after the Closing Date; (m) the Underwriters' use of i-Deal's book-building, prospectus tracking and compliance software (or other similar software) for the O ffering; and (n) the Underwriters' actual "road show" expenses for the Offering. The Underwriters may also deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or each Option Closing Date, if any, the expenses set forth herein to be paid by the Company to the Underwriters.

(b) Expenses of the Representative. The Company further agrees that, in addition to the expenses payable pursuant to Section 4.5(a), on the Closing Date, the Company will reimburse the Representative for its out-of-pocket expenses related to the Offering up to an aggregate of $70,000 (which shall include any expenses incurred under clauses (c), (m) and (n) of Section 4.5(a) herein), which shall be paid by deduction from the proceeds of the Offering contemplated herein.

4.6 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption "Use of Proceeds" in the Prospectus.

4.7 Delivery of Earnings Statements to Security Holders. The Company will timely file such reports pursuant to the Exchange Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the Securities Act.

4.8 Stabilization. Neither the Company, nor, to its knowledge, any of its employees or directors (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.9 Internal Controls. The Company will maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.10 Lock-Up Agreements. The Company shall authorize its Transfer Agent to decline to make any transfer of shares in violation of the Lock-Up Agreements.

4.11 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any 5% or greater shareholder of the Company becomes an affiliate or associated person of an Underwriter.

4.12 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase

price paid to the Company by the Underwriters for the shares and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of fiduciary duty.

4.13 Underlying Shares. The shares of Common Stock underlying the Preferred Stock shall be issued free of legends. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise at a time when such Warrant Shares would be eligible for resale under Rule 144 by a non-affiliate of the Company, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall promptly notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.14 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.15 Securities Laws Disclosure; Publicity. At the request of the Representative, by 9:00 a.m. (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any other press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity without one Business Day's prior written notice to the Representative for a period ending at 5:00 p.m. (New York City time) on the first business day following the 40th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

4.16 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, that any Underwriter of the Securities is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter

adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.17 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue the Required Minimum plus the number of Option Shares issuable pursuant to the Over-Allotment Option.

4.18 Listing of Common Stock. The Company hereby agrees to use reasonable best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Closing Shares, Option Shares and Underlying Shares on such Trading Market and promptly secure the listing of all of the Closing Shares, Option Shares and Underlying Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Closing Shares, Option Shares and Underlying Shares, and will take such other action as is necessary to cause all of the Closing Shares, Option Shares and Underlying Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to use reasonable best efforts to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.19 Subsequent Equity Sales.

(a) From the date hereof until ninety (90) days following the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents.

(b) From the date hereof until six (6) months following the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive, additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common

Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. For the avoidance of doubt, the issuance of equity awards to the Company's employees, directors and consultants under the Company's equity incentive plans, and the exercise and settlement of equity awards granted or to be granted to the Company's employees, directors and consultants under the Company's equity incentive plans, are not Variable Rate Transactions. Any Underwriter shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(c) Notwithstanding the foregoing, this Section 4.19 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.20 Research Independence. The Company acknowledges that each Underwriter's research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter's investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Closing Securities or Option Securities, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities or Option Securities, as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities or Option Securities, as the case may be, agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur does not exceed 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the other Underwriters shall

be obligated, severally, in proportion to the respective numbers of Closing Securities or Option Securities, as the case may be, which they are obligated to purchase hereunder, to purchase the Closing Securities or Option Securities, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur exceeds 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Article V, the applicable Closing Date may be postponed for such period, not exceeding seven days, as the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI.
INDEMNIFICATION

6.1 Indemnification of the Underwriters. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless the Underwriters, and each dealer selected by each Underwriter that participates in the offer and sale of the Securities (each a "Selected Dealer") and each of their respective directors, officers and employees and each Person, if any, who controls such Underwriter or any Selected Dealer ("Controlling Person") within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between such Underwriter and the Company or between such Underwriter and any third party or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) any Preliminary Prospectus, if any, the Registration Statement or the Prospectus (as from time to time each may be amended and supplemented); or (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically) ("Marketing Materials"); or (iii) any application or other document or written communication (in this Article VI, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, Trading Market or any securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon and in conformity with written information furnished to the Company with respect to the applicable Underwriter by or on behalf of such Underwriter expressly for use in any Preliminary Prospectus, if any, the Registration

Statement or Prospectus, or any amendment or supplement thereto, or in any Marketing Materials or application, as the case may be. With respect to any untrue statement or omission or alleged untrue statement or omission made in the Preliminary Prospectus, if any, the indemnity agreement contained in this Section 6.1 shall not inure to the benefit of an Underwriter to the extent that any loss, liability, claim, damage or expense of such Underwriter results from the fact that a copy of the Prospectus was not given or sent to the Person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Securities to such Person as required by the Securities Act and the rules and regulations thereunder, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under this Agreement. The Company agrees promptly to notify each Underwriter of the commencement of any litigation or proceedings against the Company or any of its officers, directors or Controlling Persons in connection with the issue and sale of the Public Securities or in connection with the Registration Statement or Prospectus.

6.2 Procedure. If any action is brought against an Underwriter, a Selected Dealer or a Controlling Person in respect of which indemnity may be sought against the Company pursuant to Section 6.1, such Underwriter, such Selected Dealer or Controlling Person, as the case may be, shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter or such Selected Dealer, as the case may be) and payment of actual expenses. Such Underwriter, such Selected Dealer or Controlling Person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter, such Selected Dealer or Controlling Person unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable fees and expenses of not more than one additional firm of attorneys selected by such Underwriter (in addition to local counsel), Selected Dealer and/or Controlling Person shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter, Selected Dealer or Controlling Person shall assume the defense of such action as provided above, the Company shall have the right to approve the terms of any settlement of such action which approval shall not be unreasonably withheld.

6.3 Indemnification of the Company. Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, its directors, officers and employees and agents who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to such Underwriter, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any Marketing Materials or application, in reliance upon, and in strict conformity with, written information furnished to the Company with respect to such Underwriter

by or on behalf of such Underwriter expressly for use in such Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any such Marketing Materials or application. In case any action shall be brought against the Company or any other Person so indemnified based on any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or any Marketing Materials or application, and in respect of which indemnity may be sought against such Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other Person so indemnified shall have the rights and duties given to such Underwriter by the provisions of this Article VI. Notwithstanding the provisions of this Section 6.3, no Underwriter shall be required to indemnify the Company for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.3 to indemnify the Company are several in proportion to their respective underwriting obligations and not joint.

6.4 Contribution.

(a) Contribution Rights. In order to provide for just and equitable contribution under the Securities Act in any case in which (i) any Person entitled to indemnification under this Article VI makes a claim for indemnification pursuant hereto but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Article VI provides for indemnification in such case, or (ii) contribution under the Securities Act, the Exchange Act or otherwise may be required on the part of any such Person in circumstances for which indemnification is provided under this Article VI, then, and in each such case, the Company and each Underwriter, severally and not jointly, shall contribute to the aggregate losses, liabilities, claims, damages and expenses of the nature contemplated by said indemnity agreement incurred by the Company and such Underwriter, as incurred, in such proportions that such Underwriter is responsible for that portion represented by the percentage that the underwriting discount appearing on the cover page of the Prospectus bears to the initial offering price appearing thereon and the Company is responsible for the balance; provided, that, no Person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section, each director, officer and employee of such Underwriter or the Company, as applicable, and each Person, if any, who controls such Underwriter or the Company, as applicable, within the meaning of Section 15 of the Securities Act shall have the same rights to contribution as such Underwriter or the Company, as applicable. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.4 to contribute are several in proportion to their respective underwriting obligations and not joint.

(b) Contribution Procedure. Within fifteen days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made

against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.4 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

ARTICLE VII.
MISCELLANEOUS

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in its opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities that materially adversely impacts the United States securities markets, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative's opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its actual and accountable out of pocket expenses related to the transactions contemplated herein then due and payable, including the fees and disbursements of PC, in an aggregate amount not

to exceed $25,000 (provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement).

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

7.2 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, and the Prospectus and the Prospectus Supplement contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. Notwithstanding anything herein to the contrary, the Investment Banking Agreement, dated October 10, 2019 ("Investment Banking Agreement"), by and between the Company and the Representative, shall continue to be effective and the terms therein, including, without limitation, Section 4(c) and Section 5 with respect to any future offerings, shall continue to survive and be enforceable by the Representative in accordance with its terms, provided that, in the event of a conflict between the terms of the Investment Banking Agreement and this Agreement, the terms of this Agreement shall prevail.

7.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail attachment at the email address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail attachment at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

7.4 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Representative. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

7.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

7.7 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any action, suit or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Article VI, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the Option Closing, if any, and the delivery of the Securities.

7.9 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

7.10 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction.

It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrict ions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.11 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Underwriters and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.12 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

7.13 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

7.14 **WAIVER OF JURY TRIAL . IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.**

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

ACHIEVE LIFE SCIENCES, INC.

By:
Name: John Bencich
Title: Chief Financial and Operating Officer

Address for Notice:
1040 West Georgia Street, Suite 1030
Vancouver, B.C. V6E 4H1, Canada
Attn:

Copy to:
Fenwick & West LLP
1191 Second Avenue, Floor 10
Seattle, WA 98101
Attn: Alan Smith

Accepted on the date first above written.
LADENBURG THALMANN & CO. INC.
As the Representative of the several
Underwriters listed on Schedule I

By:
Name: Nicholas Stergis
Title: Managing Director

Address for Notice:
4400 Biscayne Boulevard, 14th Floor
Miami, Florida 33137
Attention: General Counsel

Copy to:
Pryor Cashman LLP
7 Times Square
New York, New York 10036
Facsimile: (212) 326-0806
Attention: M. Ali Panjwani, Esq.

SCHEDULE I

Schedule of Underwriters

Underwriters	Closing Shares	Closing Preferred Shares	Closing Warrants	Closing Purchase Price
Ladenburg Thalmann & Co. Inc.				
Ladenburg Thalmann & Co. Inc.				
Total				

ACHIEVE LIFE SCIENCES, INC.

**CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS
OF
SERIES B CONVERTIBLE PREFERRED STOCK**

PURSUANT TO SECTION 151 OF THE
DELAWARE GENERAL CORPORATION LAW

The undersigned does hereby certify that:

1. He is the Chief Financial Officer of Achieve Life Sciences, Inc., a Delaware corporation (the "Corporation").

2. The Corporation is authorized to issue 5,000,000 shares of preferred stock, of which 9,158 shares of Series A Preferred Stock have been issued.

3. The following resolutions were duly adopted by a committee (the "Transaction Committee") of the board of directors of the Corporation (the "Board of Directors"):

WHEREAS, the certificate of incorporation of the Corporation provides for a class of its authorized stock known as preferred stock, consisting of 5,000,000 shares, $0.001 par value per share, issuable from time to time in one or more series;

WHEREAS, the Board of Directors is authorized to establish from time to time the number of shares to be included in each such series of preferred stock, and to fix the designation, powers, preferences and rights of the shares of each such series of preferred stock and the qualifications, limitations or restrictions thereof, and has authorized the Transaction Committee to execute such powers; and

WHEREAS, it is the desire of the Transaction Committee, pursuant to its authority as aforesaid, to fix the designation, powers, preferences, rights, qualifications, limitations, restrictions and other matters relating to a series of the preferred stock, which shall consist of, except as otherwise set forth in the Underwriting Agreement, up to [ ] shares of the preferred stock which the Corporation has the authority to issue, as follows:

NOW, THEREFORE, BE IT RESOLVED, that the Transaction Committee does hereby provide for the issuance of a series of preferred stock for cash or exchange of other securities, rights or property and does hereby fix and determine the powers, preferences, rights, qualifications, limitations, restrictions and other matters relating to such series of preferred stock as follows:

TERMS OF PREFERRED STOCK

Section 1. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"Alternate Consideration" shall have the meaning set forth in Section 7(d).

"Beneficial Ownership Limitation" shall have the meaning set forth in Section 6(d).

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Buy-In" shall have the meaning set forth in Section 6(c)(iv).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the Corporation's common stock, par value $0.001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Corporation or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Conversion Amount" means the sum of the Stated Value at issue.

"Conversion Date" shall have the meaning set forth in Section 6(a).

"Conversion Price" shall have the meaning set forth in Section 6(b).

"Conversion Shares" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Preferred Stock in accordance with the terms hereof.

"Equity Conditions" means, during the period in question, (a) the Corporation shall have duly honored all conversions scheduled to occur or occurring by virtue of one or more Notices of Conversion of the applicable Holder on or prior to the dates so requested or required, if any, (b) the Corporation shall have paid all liquidated damages and other amounts owing to the applicable Holder in respect of the Preferred Stock**,** (c) the Common Stock is trading on a Trading Market and all of the shares issuable pursuant to this

Certificate of Designation are listed or quoted for trading on such Trading Market (and the Corporation believes, in good faith, that trading of the Common Stock on a Trading Market will continue uninterrupted for the foreseeable future), (d) there is a sufficient number of authorized, but unissued and otherwise unreserved, shares of Common Stock for the issuance of all of the shares then issuable pursuant to the this Certificate of Designation, (e) the issuance of the shares in question (or, in the case of a redemption, the shares issuable upon conversion in full of the redemption amount) to the applicable Holder would not violate the limitations set forth in Section 6(d) and Section 6(e) herein**,** (f) there has been no public announcement of a pending or proposed Fundamental Transaction that has not been consummated, and (g) the applicable Holder is not in possession of any information provided by the Corporation, any of its Subsidiaries, or any of their officers, directors, employees, agents or Affiliates, that constitutes, or may constitute, material non-public information.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Fundamental Transaction" shall have the meaning set forth in Section 7(d).

"GAAP" means United States generally accepted accounting principles.

"Holder" shall have the meaning given such term in Section 2.

"Liquidation" shall have the meaning set forth in Section 5.

"New York Courts" shall have the meaning set forth in Section 8(d).

"Notice of Conversion" shall have the meaning set forth in Section 6(a).

"Original Issue Date" means the date of the first issuance of any shares of the Preferred Stock regardless of the number of transfers of any particular shares of Preferred Stock and regardless of the number of certificates which may be issued to evidence such Preferred Stock.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Preferred Stock" shall have the meaning set forth in Section 2.

"Representative" means Ladenburg Thalmann & Co. Inc.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Share Delivery Date" shall have the meaning set forth in Section 6(c).

"Stated Value" shall have the meaning set forth in Section 2, as the same may be increased pursuant to Section 3.

"Successor Entity" shall have the meaning set forth in Section 7(d).

"Trading Day" means a day on which the principal Trading Market is open for business.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means American Stock Transfer & Trust Company, LLC, the current transfer agent of the Corporation with a mailing address of 6201 15th Avenue, Brooklyn, New York 11219, Attn: 2 nd Floor, Reorganization Department, and an email address of ReorgWarrants@ASTFINANCIAL.com, and any successor transfer agent of the Corporation.

"Underwriting Agreement" means the underwriting agreement, dated as of [ ] 2019, among the Corporation and the Representative, as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Preferred Stock then outstanding and reasonably acceptable to the Corporation, the fees and expenses of which shall be paid by the Corporation.

Section 2. Designation, Amount and Par Value. The series of preferred stock shall be designated as its Series B Convertible Preferred Stock (the "Preferred Stock") and the number of shares so designated shall be up to [ ] (which shall not be subject to increase without the written consent of 67% of the holders of the Preferred Stock (each, a "Holder" and collectively, the "Holders")). Each share of Preferred Stock shall have a par value of $0.001 per share and a

stated value equal to $1,000, subject to increase set forth in Section 3 below (the "Stated Value"). The Preferred Stock will initially be issued in book-entry form and shall initially be represented only by one or more global certificates deposited with the Depository Trust Company ("DTC") and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. As between the Corporation and a beneficial owner of Preferred Stock shall have all of the rights and remedies of a Holder hereunder. In addition, a beneficial owner of Preferred Stock has the right, upon written notice by such beneficial owner to the Corporation, to request the exchange of some or all of such beneficial owner's interest in Preferred Stock represented by one or more global Preferred Stock certificates deposited with Cede & Co. (or its successor) for a physical Preferred Stock certificate (a "Preferred Stock Certificate Request Notice" and the date of delivery of such Preferred Stock Certificate Request Notice by a beneficial owner, the "Preferred Stock Certificate Request Notice Date" and the deemed surrender upon delivery by the beneficial owner of a number of global shares of Preferred Stock for the same number of shares of Preferred Stock represented by a physical stock certificate, a "Preferred Stock Exchange", and such physical certificate(s), a "Preferred Stock Certificate"). Upon delivery of a Preferred Stock Certificate Request Notice, the Corporation shall promptly effect the Preferred Stock Exchange and shall promptly issue and deliver to the beneficial owner a physical Preferred Stock Certificate for such number of shares of Preferred Stock represented by its interest in such global certificates in the name of the beneficial owner. Such Preferred Stock Certificate shall be dated the original issue date and shall be executed by an authorized signatory of the Corporation. In connection with a Preferred Stock Exchange, the Corporation agrees to deliver the Preferred Stock Certificate to the Holder within three (3) Business Days of the delivery of a properly completed and executed Preferred Stock Certificate Request Notice pursuant to the delivery instructions in the Preferred Stock Certificate Request Notice. The Corporation covenants and agrees that, upon the date of delivery of the properly completed and executed Preferred Stock Certificate Request Notice, the Holder shall be deemed to be the holder of the Preferred Stock Certificate and further, for purposes of Regulation SHO, a Holder whose interest in this Preferred Stock is a beneficial interest in certificate(s) representing this Preferred Stock held in book-entry form through DTC shall be deemed to have converted its interest in this Preferred Stock upon instructing its broker that is a DTC participant to convert its interest in this Preferred Stock, and, notwithstanding anything to the contrary set forth herein, the Preferred Stock Certificate shall be deemed for all purposes to represent all of the terms and conditions of the Preferred Stock evidenced by such global Preferred Stock certificates and the terms hereof.

Section 3. Dividends. Except for stock dividends or distributions for which adjustments are to be made pursuant to Section 7, Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of Preferred Stock equal (on an as-if-converted-to-Common-Stock basis, disregarding for such purpose any conversion limitations hereunder) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be paid on shares of Preferred Stock. The Corporation shall not pay any dividends on the Common Stock unless the Corporation simultaneously complies with this provision.

Section 4. Voting Rights. Except as otherwise provided herein or as otherwise required by law, the Preferred Stock shall have no voting rights. However, as long as any shares of Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the

Holders of a majority of the then outstanding shares of the Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or alter or amend this Certificate of Designation, (b) amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the Holders, (c) increase the number of authorized shares of Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Section 5. Liquidation. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "Liquidation"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to Common Stock which amounts shall be paid pari passu with all holders of Common Stock. The Corporation shall mail written notice of any such Liquidation, not less than 45 days prior to the payment date stated therein, to each Holder.

Section 6. Conversion.

Conversions **a)** Option of Holder. Each share of Preferred Stock shall be convertible, at any time and from time to time from and after the Original Issue Date at the option of the Holder thereof, into that number of shares of Common Stock (subject to the limitations set forth in Section 6(d)) determined by dividing the Stated Value of such share of Preferred Stock by the Conversion Price. Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as Annex A (a "Notice of Conversion"). Each Notice of Conversion shall specify the number of shares of Preferred Stock to be converted, the number of shares of Preferred Stock owned prior to the conversion at issue, the number of shares of Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable Holder delivers by e-mail such Notice of Conversion to the Corporation (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion to the Corporation is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. The calculations and entries set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error. To effect conversions of shares of Preferred Stock, a Holder shall not be required to surrender the certificate(s) representing the shares of Preferred Stock to the Corporation unless all of the shares of Preferred Stock represented thereby are so converted, in which case such Holder shall deliver the certificate representing such shares of Preferred Stock promptly following the Conversion Date at issue. Shares of Preferred Stock converted into Common Stock or redeemed in accordance with the terms hereof shall be canceled and shall not be reissued. Notwithstanding the foregoing in this Section 6(a), a holder whose interest in the Preferred Stock is a beneficial interest in certificate(s) representing the Preferred Stock held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect conversions made pursuant to this Section 6(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for conversion, complying with

the procedures to effect conversions that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive Preferred Stock in certificated form pursuant to Section 2, in which case this sentence shall not apply.

Conversion Price. The conversion price for the Preferred Stock shall equal $[ ], subject to adjustment herein (the "Conversion Price").

c) Mechanics of Conversion

Delivery of Conversion Shares Upon Conversion. Not later than the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) after each Conversion Date (the "Share Delivery Date"), the Corporation shall deliver, or cause to be delivered, to the converting Holder (A) the number of Conversion Shares being acquired upon the conversion of the Preferred Stock, which Conversion Shares shall be free of restrictive legends and trading restrictions, and (B) a bank check in the amount of accrued and unpaid dividends, if any. The Corporation shall use its best efforts to deliver the Conversion Shares required to be delivered by the Corporation under this Section 6 electronically through the Depository Trust Company or another established clearing corporation performing similar functions. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Corporation's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Conversion. Notwithstanding the foregoing, with respect to any Notice(s) of Conversion delivered by 10:00 a.m. (New York City time) on the Original Issue Date, the Corporation agrees to deliver the Conversion Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Original Issue Date, with the Original Issue Date being deemed the "Share Delivery Date" with respect to any Notice(s) of Conversion.

Failure to Deliver Conversion Shares. If, in the case of any Notice of Conversion, such Conversion Shares are not delivered to or as directed by the applicable Holder by the Share Delivery Date, the Holder shall be entitled to elect by written notice to the Corporation at any time on or before its receipt of such Conversion Shares, to rescind such Conversion, in which event the Corporation shall promptly return to the Holder any original Preferred Stock certificate delivered to the Corporation and the Holder shall promptly return to the Corporation the Conversion Shares issued to such Holder pursuant to the rescinded Notice of Conversion.

Obligation Absolute; Partial Liquidated Damages. The Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff,

counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares; provided, however, that such delivery shall not operate as a waiver by the Corporation of any such action that the Corporation may have against such Holder. In the event a Holder shall elect to convert any or all of the Stated Value of its Preferred Stock, the Corporation may not refuse conversion based on any claim that such Holder or any one associated or affiliated with such Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and/or enjoining conversion of all or part of the Preferred Stock of such Holder shall have been sought and obtained. In the absence of such injunction, the Corporation shall issue Conversion Shares and, if applicable, cash, upon a properly noticed conversion. If the Corporation fails to deliver to a Holder such Conversion Shares pursuant to Section 6(c)(i) by the Share Delivery Date applicable to such conversion, the Corporation shall pay to such Holder, in cash, as liquidated damages and not as a penalty, for each $5,000 of Stated Value of Preferred Stock being converted, $50 per Trading Day (increa sing to $100 per Trading Day on the third Trading Day and increasing to $200 per Trading Day on the sixth Trading Day after such damages begin to accrue) for each Trading Day after the Share Delivery Date until such Conversion Shares are delivered or Holder rescinds such conversion. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

Compensation for Buy-In on Failure to Timely Deliver Conversion Shares Upon Conversion. In addition to any other rights available to the Holder, if the Corporation fails for any reason to deliver to a Holder the applicable Conversion Shares by the Share Delivery Date pursuant to Section 6(c)(i), and if after such Share Delivery Date such Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by such Holder of the Conversion Shares which such Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "Buy-In"), then the Corporation shall (A) pay in cash to such Holder (in addition to any other remedies available to or elected by such Holder) the amount, if any, by which (x) such Holder's total purchase price (including any brokerage commissions) for the Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that such Holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order

giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such Holder, either reissue (if surrendered) the shares of Preferred Stock equal to the number of shares of Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such Holder the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(c)(i). For example, if a Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of shares of Preferred Stock with respect to which the actual sale price of the Conversion Shares (including any brokerage commissions) giving rise to such purchase obligation was a total of $10,000 under clause (A) of the immediately preceding sentence, the Corporation shall be required to pay such Holder $1,000. The Holder shall provide the Corporation written notice indicating the amounts payable to such Holder in respect of the Buy-In and, upon request of the Corporation, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Corporation's failure to timely deliver the Conversion Shares upon conversion of the shares of Preferred Stock as required pursuant to the terms hereof.

Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Preferred Stock as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holder (and the other holders of the Preferred Stock), not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments and restrictions of Section 7) upon the conversion of the then outstanding shares of Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable.

Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Preferred Stock. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share. Notwithstanding anything to the contrary contained herein, but consistent with the provisions of this subsection with respect to fractional Conversion Shares, nothing shall prevent any Holder from converting fractional shares of Preferred Stock.

Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the

issue or delivery of such Conversion Shares, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holders of such shares of Preferred Stock and the Corporation shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid. The Corporation shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Conversion Shares.

(d) Beneficial Ownership Limitation. The Corporation shall not effect any conversion of the Preferred Stock, and a Holder shall not have the right to convert any portion of the Preferred Stock, to the extent that, after giving effect to the conversion set forth on the applicable Notice of Conversion, such 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 (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (i) conversion of the remaining, unconverted Stated Value of Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, the Preferred Stock) beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 6(d), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder provided that the Corporation makes no representation to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and that the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 6(d) applies, the determination of whether the Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to the Corporation each time it delivers a Notice of Conversion that such Notice of Conversion has not violated the restrictions set

forth in this paragraph and the Corporation shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 6(d), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request (which may be via email) of a Holder, the Corporation shall within two (2) Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any shares of Preferred Stock, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Stock held by the applicable Holder. A Holder, upon notice to the Corporation, may increase or decrease the Bene ficial Ownership Limitation provisions of this Section 6(d) applicable to its Preferred Stock provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of this Preferred Stock held by the Holder and the provisions of this Section 6(d) shall continue to apply. Any such increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Corporation and shall only apply to such Holder and no other Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6(d) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to s uch limitation. The limitations contained in this paragraph shall apply to a successor holder of Preferred Stock.

e) Forced Conversion. Notwithstanding anything herein to the contrary, if after the Original Issue Date, (i) the VWAP during any 30 consecutive Trading Day period, which thirty (30) consecutive Trading Day period shall have commenced only after the Original Issue Date (the "Threshold Period"), exceeds $[ ] (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like after the Original Issue Date), and (ii) the average daily dollar trading volume for such Threshold Period exceeds $500,000 per Trading Day, then the Corporation may, within one (1) Trading Day after the end of any such Threshold Period, deliver a written notice to all Holders (a "Forced Conversion Notice" and the date such notice is delivered to all Holders, the "Forced Conversion Notice Date") to cause each Holder to convert all or part of such Holder's Preferred Stock (as specified in such Forced Conversion Notice) pursuant to

Section 6, it being agreed that the "Conversion Date" for purposes of Section 6 shall be deemed to occur on the third Trading Day following the Forced Conversion Notice Date (such third Trading Day, the "Forced Conversion Date"). The Corporation may not deliver a Forced Conversion Notice, and any Forced Conversion Notice delivered by the Corporation shall not be effective, unless all of the Equity Conditions have been met on each Trading Day during the applicable Threshold Period through and including the later of the Forced Conversion Date and the Trading Day after the date that the Conversion Shares issuable pursuant to such conversion are actually delivered to the Holders pursuant to the Forced Conversion Notice. Any Forced Conversion Notices shall be applied ratably to all of the Holders based on the then outstanding shares of Preferred Stock. For purposes of clarification, a Forced Conversion shall be subject to all of the provisions of Section 6, including, without limitation, the provisions requiring payment of liquidated damages and limitations on conversions.

Section 7. Certain Adjustments.

(a) Stock Dividends and Stock Splits. If the Corporation, at any time while this Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of, or payment of a dividend on, this Preferred Stock), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 7(a) above, if at any time the Corporation grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder of will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of such Holder's Preferred Stock (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided,

however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Preferred Stock, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Preferred Stock (without regard to any limitations on conversion hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Preferred Stock is outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person, (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Corporation, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted i nto or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person

whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent conversion of this Preferred Stock, the Holder shall have the right to receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of this Preferred Stock), the number of shares of Common Stock of the successor or acquiring corporation or of the Corporation, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Preferred Stock is convertible immediately prior to such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of this Preferred Stock). For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall apportion the Conversion Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation with the same terms and conditions and issue to the Holders new preferred stock consistent with the foregoing provisions and evidencing the Holders' right to convert such preferred stock into Alternate Consideration. The Corporation shall cause any successor entity in a Fundamental Transaction in which the Corporation is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Corporation under this Certificate of Designation in accordance with the provisions of this Section 7(d) and shall, at the option of the Holder, deliver to the Holder in exchange for this Preferred Stock a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Preferred Stock which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon conversion of this Preferred Stock (without regard to any limitations on the conversion of this Preferred Stock) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of this Preferred Stock immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Certificate of Designation referring

to the "Corporation" shall refer instead to the Successor Entity), and may exercise every right and power of the Corporation and shall assume all of the obligations of the Corporation under this Certificate of Designation with the same effect as if such Successor Entity had been named as the Corporation herein.

Calculations. (e) All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

Notice to the Holders. (f)

Adjustment to Conversion Price. (i) Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder by facsimile or email a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

Notice to Allow Conversion by Holder. (ii) If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liqui dation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Preferred Stock, and shall cause to be delivered by facsimile or email to each Holder at its last facsimile number or email address as it shall appear upon the stock books of the Corporation, at least ten (10) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange, provided that the failure to deliver such notice or any defect therein or in the delivery thereof

shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Corporation or any of the Subsidiaries, the Corporation shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to convert the Conversion Amount of this Preferred Stock (or any part hereof) during the period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 8. Miscellaneous.

(a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Corporation, at the address set forth below: Achieve Life Sciences, Inc., c/o 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1, Canada, Attention: Senior Paralegal, e-mail address sthomson@achievelifesciences.com, or such other e-mail address or address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section 8. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile, e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Corporation. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail at the e-mail address set forth in this Section 8 prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. Notwithstanding any other provision of this Certificate of Designation, as to any Preferred Stock not held in certificated form, where this Certificate of Designation provides for notice of any event to a Holder, such notice shall be sufficiently given if given to DTC (or any successor depository) pursuant to the procedures of DTC (or such successor depository).

(b) Absolute Obligation. Except as expressly provided herein, no provision of this Certificate of Designation shall alter or impair the obligation of the Corporation, which is absolute and unconditional, to pay liquidated damages, and accrued dividends, as applicable, on the shares of Preferred Stock at the time, place, and rate, and in the coin or currency, herein prescribed.

(a) Lost or Mutilated Preferred Stock Certificate. If a Holder's Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation.

(b) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware without regard to the principles of conflict of laws thereof. All legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by this Certificate of Designation (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in the City of New York, Borough of Manhattan (the "New York Courts"). The Corporation and each Holder hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such New York Courts, or such New York Courts are improper or inconvenient venue for such proceeding. The Corporation and each Holder hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. The Corporation and each Holder hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If the Corporation or any Holder shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

(c) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

(h) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

(i) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

(j) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

(k) Status of Converted or Redeemed Preferred Stock. If any shares of Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series B Convertible Preferred Stock.

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RESOLVED, FURTHER, that the Chairman, the president or any vice-president, and the secretary or any assistant secretary, of the Corporat ion be and they hereby are authorized and directed to prepare and file this Certificate of Designation of Preferences, Rights and Limitations in accordance with the foregoing resolution and the provisions of Delaware law.

IN WITNESS WHEREOF, the undersigned has executed this Certificate this [ ]th day of [ ] 2019.

By: _____
Name:
Title:

ANNEX A

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO CONVERT SHARES OF PREFERRED STOCK)

The undersigned hereby elects to convert the number of shares of Series B Convertible Preferred Stock indicated below into shares of common stock, par value $0.001 per share (the "Common Stock"), of Achieve Life Sciences, Inc., a Delaware corporation (the "Corporation"), according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a Person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto. No fee will be charged to the Holders for any conversion, except for any such transfer taxes.

Conversion calculations:

Date to Effect Conversion: _____

Number of shares of Preferred Stock owned prior to Conversion: _____

Number of shares of Preferred Stock to be Converted: _____

Stated Value of shares of Preferred Stock to be Converted: _____

Number of shares of Common Stock to be Issued: _____

Applicable Conversion Price:_____

Number of shares of Preferred Stock subsequent to Conversion: _____

Address for Delivery: _____
or
DWAC Instructions:
Broker no: _____
Account no: _____

HOLDER

By:_____
Name:
Title:

COMMON STOCK PURCHASE WARRANT

ACHIEVE LIFE SCIENCES, INC.

Warrant Shares: _____ Initial Exercise Date: [ ], 2019

CUSIP:

ISIN:

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, CEDE & CO. or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date ") and on or prior to 5:00 p.m. (New York City time) on [ ], 2024 (the "Termination Date") but not thereafter, to subscribe for and purchase from Achieve Life Sciences, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of this Warrant, subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in

good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Registration Statement" means the Company's registration statement on Form S-1 (File No. 333-234530).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing.

"Transfer Agent" means American Stock Transfer & Trust Company, LLC, the current transfer agent of the Company, with a mailing address of 6201 15th Avenue, Brooklyn, New York 11219 and an email address of **ReorgWarrants@ASTFINANCIAL.com**, and any successor transfer agent of the Company.

"Underwriting Agreement" means the underwriting agreement, dated as of [ ], 2019 among the Company and Ladenburg Thalmann & Co. Inc. as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrant Agency Agreement" means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

"Warrant Agent" means the Transfer Agent and any successor warrant agent of the Company.

"Warrants" means this Warrant and other warrants to purchase Common Stock issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (with a copy to the Transfer Agent (or such other office or agency that the Company may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other

type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **$[ ]**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(68) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on

the principal Trading Market as reported by Bloomberg L.P. as of the time of the Ho lder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise, and, in the case of each of (i) and (iii), subject to the Company's receipt of the aggregate Exercise Price (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record

of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise, and the Company shall return all consideration paid by the Holder for such shares upon such rescission. Notwithstanding anything herein to the contrary, the Company shall not be required to make any cash payments to the Holder in lieu of issuance of the Warrant Shares.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by

the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day

processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to the Company each time it delivers a Notice of Exercise that such Notice of Exercise has not violated the restrictions set forth in this paragraph, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most

recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two (2) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

f) Call Provision. Subject to the provisions of Section 2(e) and this Section 2(f), if, after the Initial Exercise Date, (i) the VWAP for any 30 consecutive Trading Days (the "Measurement Period," which 30 consecutive Trading Day period shall not have commenced until after the Initial Exercise Date) exceeds **$[ ]** (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 Holder is not in possession of any information that constitutes, or might constitute, material non-public information which was provided by the Company, any of its subsidiaries, or any of their officers, directors, employees, agents or Affiliates, then the Company may, within 1 Trading Day of the end of any such Measurement Period, call for cancellation of all or any portion of this Warrant for which a Notice of Exercise has not yet been delivered (such right, a "Call") for consideration equal to $0.001 per Warrant Share. To exercise this right, the Company must deliver to the Holder an irrevocable written notice (a "Call Notice"), indicating therein the portion of unexercised portion of this Warrant to which such notice applies. If the conditions set forth below for such Call are satisfied from the period from the date of the Call Notice through and including the Call Date (as defined below), then any portion of this Warrant subject to such Call Notice for which a Notice of Exercise shall not have been received by the Call Date will be cancelled at 6:30 p.m. (New York City time) on the tenth Trading Day after the date the Call Notice is received by the Holder (such date and time, the "Call Date"). Any unexercised portion of this Warrant to which the Call Notice does not pertain will be

unaffected by such Call Notice. In furtherance thereof, the Company covenants and agrees that it will honor all Notices of Exercise with respect to Warrant Shares subject to a Call Notice that are tendered through 6:30 p.m. (New York City time) on the Call Date. The parties agree that any Notice of Exercise delivered following a Call Notice which calls less than all of the Warrants shall first reduce to zero the number of Warrant Shares subject to such Call Notice prior to reducing the remaining Warrant Shares available for purchase under this Warrant. For example, if (A) this Warrant then permits the Holder to acquire 100 Warrant Shares, (B) a Call Notice pertains to 75 Warrant Shares, and (C) prior to 6:30 p.m. (New York City time) on the Call Date the Holder tenders a Notice of Exercise in respect of 50 Warrant Shares, then (x) on the Call Date the right under this Warrant to acquire 25 Warrant Shares will be automatically cancelled, (y) the Company, in the time and manner required under this Warrant, will have issued and delivered to the Holder 50 Warrant Shares in respect of the exercises following receipt of the Call Notice, and (z) the Holder may, until the Termination Date, exercise this Warrant for 25 Warrant Shares (subject to adjustment as herein provided and subject to subsequent Call Notices). Subject again to the provisions of this Section 2(f), the Company may deliver subsequent Call Notices for any portion of this Warrant for which the Holder shall not have delivered a Notice of Exercise. Notwithstanding anything to the contrary set forth in this Warrant, the Company may not deliver a Call Notice or require the cancellation of this Warrant (and any such Call Notice shall be void), unless, from the beginning of the Measurement Period through the Call Date, (1) the Company shall have honored in accordance with the terms of this Warrant all Notices of Exercise delivered by 6:30 p.m. (New York City time) on the Call Date, and (2) a registration statement shall be effective as to all Warrant Shares and the prospectus thereunder available for use by the Company for the sale of all such Warrant Shares to the Holder, and (3) the Common Stock shall be listed or quoted for trading on the Trading Market, and (4) there is a sufficient number of authorized shares of Common Stock for issuance of all Warrant Shares, and (5) the issuance of all Warrant Shares subject to a Call Notice shall not cause a breach of any provision of Section 2(e) herein. The Company's right to call the Warrants under this Section 2(f) shall be exercised ratably among the Holders based on each Holder's initial purchase of Warrants.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this

Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Reserved.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever,

as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) or Section 2(f) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) or Section 2(f) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction other than one in which a Successor Entity (as defined below) that is a publicly traded corporation whose stock is quoted or listed on a Trading Market assumes this Warrant such that the Warrant shall be exercisable for the publicly traded common stock of such Successor Entity, the Company or any Successor Entity shall, at the

Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction, purchase this Warrant from the Holder by paying to the Holder an amount equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction using the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. Any cash payment will be made by wire transfer of immediately available funds within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). "Black Scholes Value" means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any

of its subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depositary), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company or the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day or Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day or Trading Day, as the case may be.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without

limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1 Canada, Attention: Senior Paralegal, email address: sthomson@achievelifesciences.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. Notwithstanding any other provision of this Warrant, as to any Warrant not held in certificated form, where this Warrant provides for notice of any event to a Holder, such notice shall be sufficiently given if given to DTC (or any successor depository) pursuant to the procedures of DTC (or such successor depository).

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holders or the beneficial owners of Warrants representing 67% of the Warrant Shares issuable under the Warrants then-outstanding as of the date such consent is sought, on the other hand .

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depositary), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ACHIEVE LIFE SCIENCES, INC.

By:_____
Name:
Title:

NOTICE OF EXERCISE

TO: ACHIEVE LIFE SCIENCES, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity:
Signature of Authorized Signatory of Investing Entity:
Name of Authorized Signatory:
Title of Authorized Signatory:
Date:

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:
(Please Print)

Address:
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature:

Holder's Address:

LOCK-UP AGREEMENT

_____, 2019

Ladenburg Thalmann & Co. Inc.,
acting as representative to the several underwriters:

Re: Underwriting Agreement, by and between Achieve Life Sciences, Inc. and Ladenburg Thalmann & Co. Inc., acting as representative to the several underwriters

Ladies and Gentlemen:

The undersigned irrevocably agrees with the Company that, from the date hereof until 90 days following the date of the Underwriting Agreement (the "Underwriting Agreement") entered into by and between Achieve Life Sciences, Inc. (the "Company") and Ladenburg Thalmann & Co. Inc. (the "Representative"), acting as representative to the several underwriters (such period, the "Restriction Period" and the underwriters collectively, the "Underwriters"), the undersigned will not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the undersigned or any Affiliate (as defined in the Underwriting Agreement) of the undersigned or any person in privity with the undersigned or any Affiliate of the undersigned), directly or indirectly, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), with respect to, any shares of common stock of the Company or securities convertible, exchangeable or exercisable into, shares of common stock of the Company beneficially owned, held or hereafter acquired by the undersigned (the "Securities"). Beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act. In order to enforce this covenant, the Company shall impose irrevocable stop-transfer instructions preventing the transfer agent of the Company from effecting any actions in violation of this letter agreement. The Representative may consent to an early release from the Restriction Period if, in its sole and absolute discretion, the market for the Securities would not be adversely impacted by sales and in cases of financial emergency. The restrictions contained in this letter agreement shall not apply to the Securities to be sold pursuant to the Underwriting Agreement on behalf of the undersigned, if any. Notwithstanding the foregoing, if (i) the Company issues an earnings release or material news, or a material event relating to the Company occurs, during the last 17 days of the Restriction Period, or (ii) prior to the expiration of the Restriction Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Restriction Period, the restrictions imposed by this letter agreement shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, unless the Representative waives such extension.

Notwithstanding any of the foregoing, the restrictions set forth in the immediately preceding paragraph shall not apply to (i) any transfers made by the undersigned (a) as a bona fide gift to

any member of the immediate family (as defined below) of the undersigned or to a trust the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family, (b) by will or intestate succession upon the death of the undersigned, or (c) as a bona fide gift to a charity or educational institution, *provided, however*, that (A) it shall be a condition to the transfer that the transferee executes and delivers to the Representatives written agreement, in substantially the form of this Agreement (it being understood that any references to "immediate family" in the agreement executed by such transferee shall expressly refer only to the immediate family of the undersigned and not to the immediate family of the transferee), and (B) if the undersigned is required to file a report under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of Securities during the Restriction Period, the undersigned shall include a statement in such report to the effect that, in the case of any such transfer, such transfer is being made as a gift or by will or intestate succession, as the case may be, (ii) transactions relating to Securities acquired in open market transactions after the completion of the proposed public offering, provided that no filing under Section 16(a) of the Exchange Act, or the rules promulgated thereunder, shall be required or shall be voluntarily made during the Restriction Period in connection with subsequent sales of Securities acquired in such open market transactions, (iii) the transfer to the Company of Securities upon a vesting event of the Company's securities or upon the exercise of options or warrants to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax withholding obligations of the undersigned in connection with such vesting or exercise, provided that any related filing under Section 16(a) of the Exchange Act reporting a disposition of Securities made in connection with such vesting or exercise shall contain a description of the transaction and indicate that the disposition was made as part of such vesting or exercise or to cover tax withholding obligations in connection therewith, (iv) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act (a "10b5-1 Plan") for the transfer of Securities, provided that such plan does not provide for the transfer of Securities during the Restriction Period and no public announcement or filing under the Exchange Act regarding the establishment of such plan shall be required of or voluntarily made by or on behalf of the undersigned or the Company (v) the transfer of Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, and (vi) pursuant to the transfer, sale, tender or other disposition of Securities to a bona fide third party pursuant to a tender offer for securities of the Company made to all stockholders of the Company, or any merger, consolidation, stock exchange or other business combination that results in all of the Company's stockholders having the right to exchange their Securities for cash, securities or other property, in each case that is approved by the independent members of the Board of Directors of the Company and involves a change in ownership of a majority of the voting capital stock of the Company; provided that in the event that the tender offer, merger, consolidation, stock exchange or other business combination is not completed, the Securities owned by the undersigned shall remain subject to the restrictions in this lock-up agreement. For purposes of this paragraph, "immediate family" shall mean a spouse, domestic partner, sibling, parent, stepparent, grandparent, child, stepchild, grandchild or other lineal descendant (including by adoption), father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of the undersigned. The undersigned acknowledges that the execution, delivery and performance of this letter agreement is a material inducement to each Underwriter to perform under the Underwriting Agreement and that each Underwriter (which shall be a third party beneficiary of this letter agreement) and the Company shall be entitled to specific performance of the undersigned's obligations hereunder. The

undersigned hereby represents that the undersigned has the power and authority to execute, deliver and perform this letter agreement, that the undersigned has received adequate consideration therefor and that the undersigned will indirectly benefit from the closing of the transactions contemplated by the Underwriting Agreement.

This letter agreement may not be amended or otherwise modified in any respect without the written consent of each of the Company, the Representative and the undersigned. This letter agreement shall be construed and enforced in accordance with the laws of the State of New York without regard to the principles of conflict of laws. The undersigned agrees and understands that this letter agreement does not intend to create any relationship between the undersigned and each Underwriter and that no issuance or sale of the Securities is created or intended by virtue of this letter agreement.

Except as set forth herein, this letter agreement shall be binding on successors and assigns of the undersigned with respect to the Securities and any such successor or assign shall enter into a similar agreement for the benefit of the Underwriters.

It is understood that, if (i) the Company notifies the Representative that it does not intend to proceed with the proposed public offering, (ii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities to be sold thereunder, or (iii) the Underwriting Agreement shall not have been signed by December 31, 2019, this Agreement shall immediately be terminated and the undersigned shall be released from all obligations under this Agreement.

*** SIGNATURE PAGE FOLLOWS***

This letter agreement may be executed in two or more counterparts, all of which when taken together may be considered one and the same agreement.

_____
Signature

_____
Print Name

_____
Position in Company, if any

Address for Notice:

Exhibit 5.1

FENWICK & WEST LLP
1191 SECOND AVENUE, 10TH FLOOR SEATTLE, WA 98101
TEL: 206.389.4510 FAX: 206.389.4511 WWW.FENWICK.COM

December 2, 2019

Achieve Life Sciences, Inc.
1001 W. Broadway, Suite 400
Vancouver, BC V6H 4B1

Gentlemen/Ladies:

We have acted as counsel to Achieve Life Sciences, Inc., a Delaware corporation (the "***Company***"), in connection with the registration statement on Form S-1 (File No. 333-234530) filed with the Securities and Exchange Commission (the "***Commission***") on November 6, 2019, and each amendment thereto (the "***Registration Statement***"), relating to the registration under the Securities Act of 1933, as amended (the "***Act***"), of up to (i) 4,347,826 Class A Units (the "***Class A Units***"), with each Class A Unit consisting of one share of the Company's common stock, par value $0.001 per share ("***Common Stock***"), and a warrant to purchase one share of Common Stock; (ii) 16,014 Class B Units (the "***Class B Units***" and together with the Class A Units, the "***Units***"), with each Class B Unit consisting of one share of the Company's Series B convertible preferred stock, par value $0.001 per share ("***Series B Preferred Stock***"), and a warrant to purchase a number of shares of Common Stock equal to $999.12 divided by the conversion price of the Series B Preferred Stock, with each Class B Unit to be offered to the public at an offering price of $999.12 per Class B Unit; (iii) shares of Common Stock issuable upon conversion of the shares of Series B Preferred Stock and (iv) shares of Common Stock issuable upon exercise of the warrants (the "***Warrant Shares***") issued under each of the Class A Units and the Class B Units (each a "***Warrant***" and together the "***Warrants***"). The shares of Common Stock included in the Class A Warrants, the Warrants and the Series B Preferred Stock, including the shares of Common Stock issuable upon the conversion of the Series B Preferred Stock, are collectively referred to herein as the "***Securities***." The Units are to be sold by the Company pursuant to an underwriting agreement (the "***Underwriting Agreement***") to be entered into by and between the Company and Ladenburg Thalmann & Co., Inc. The Securities are to be offered and sold in the manner described in the Registration Statement and the related prospectus included therein (the "***Prospectus***").

In connection with our opinion expressed below we have examined originals or copies of the Company's certificate of incorporation, as amended (the "***Certificate***") and bylaws, as amended (the "***Bylaws***"), certain corporate proceedings of the Company's board of directors (the "***Board***") and stockholders relating to the Registration Statement and the Prospectus, the Series B Certificate of Designation, the Warrant, the Underwriting Agreement and such other agreements, documents, certificates and statements of the Company, its transfer agent and public or government officials, as we have deemed advisable, and have examined such questions of law as we have considered necessary. We have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures on documents submitted to us, the conformity to originals of all documents submitted to us as copies, and the absence of any undisclosed termination, waiver or amendment to any document reviewed by us. In giving our opinion, we have also relied upon a good standing certificate regarding the Company issued by the Delaware Secretary of State and representations made to us by the Company.

We render this opinion only with respect to, and express no opinion herein concerning the application or effect of the laws of any jurisdiction other than, the (i) existing Delaware General Corporation Law of the State of Delaware and (ii) existing laws of the State of Washington (the "***Applicable Laws***"). To the extent that the Warrants are governed by the laws of any jurisdiction other than the State of Washington, our opinion expressed below assumes that Internal Washington Law (as defined below) will exclusively apply to and govern such Warrant Agreement,

without regard to any interpretation or construction that might be indicated by the laws stated as governing any such Warrant Agreement. As used herein "***Internal Washington Law***" means the internal laws of the State of Washington applicable to a contract made by Washington residents in the State of Washington that selects Washington law as the governing law of such contract, without regard to any laws or equitable principles regarding choice of law, conflict of laws or public policies that might make any other law(s) applicable.

Based upon, and subject to, the foregoing, we are of the opinion that:

1. The Class A Units and the Class B Units, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

2. The shares of Common Stock included in the Class A Units, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

3. The shares of Series B Preferred Stock included in the Class B Units, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

4. The shares of Common Stock, when issued upon conversion of the shares of Series B Preferred Stock, will be validly issued, fully paid and non-assessable.

5. The Warrants, when issued as set forth in the Registration Statement will be legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their terms.

6. The Warrant Shares, when issued upon exercise of the Warrants against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

We consent to the use of this opinion as an exhibit to the Registration Statement and further consent to all references to us, if any, in the Registration Statement, the Prospectus constituting a part thereof and any amendments thereto. We do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder. This opinion is intended solely for use in connection with the issuance and sale of the Securities subject to the Registration Statement and is not to be relied upon for any other purpose. In providing this opinion, we are opining only as to the specific legal issues expressly set forth above, and no opinion shall be inferred as to any other matter or matters. This opinion is rendered on, and speaks only as of, the date first written above, and does not address any potential change in facts or law that may occur after the date of this opinion. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention, whether or not such occurrence would affect or modify any of the opinions expressed herein.

[Signature Page Follows]

Very truly yours,

/s/ Fenwick & West LLP

FENWICK & WEST LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in this Amendment No. 1 to the Registration Statement on Form S-1 (No. 333-234530) of Achieve Life Sciences, Inc. of our report dated March 14, 2019 relating to the consolidated financial statements of Achieve Life Sciences, Inc., which appears in Achieve Life Sciences Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Chartered Professional Accountants
Vancouver, British Columbia, Canada
December 2, 2019