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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019
Or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number 033-80623

Achieve Life Sciences, Inc.

(Exact name of the registrant as specified in its charter)

Delaware	**95-4343413**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1040 West Georgia Street, Suite 1030, Vancouver, B.C. V6E 4H1
(Address of principal executive offices, including zip code)

(604) 210-2217
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	ACHV	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.). Yes ☐ No ☒

As of June 30, 2019, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was $15,103,249, computed with reference to the price at which the Common Stock was last sold on June 30, 2019. As of March 13, 2020, 31,352,764 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement for its 2020 Annual Meeting of Stockholders ("Proxy Statement"), to be filed within 120 days of the Registrant's fiscal year ended December 31, 2019, is incorporated by reference into Part III of this Annual Report on Form 10-K.

Achieve Life Sciences, Inc.

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PART I

References in this Form 10-K to "Achieve Life Sciences," "Achieve," the "Company," "we," "us" or "our" refer to Achieve Life Sciences, Inc. and its wholly owned subsidiaries. The information in this Annual Report on Form 10-K contains certain forward-looking statements, including statements related to clinical trials, regulatory approvals, markets for our products, new product development, capital requirements and trends in our business that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as those discussed elsewhere in this Annual Report on Form 10-K.

ITEM 1. BUSINESS

OVERVIEW OF OUR BUSINESS AND RECENT DEVELOPMENTS

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.

Our management team has significant experience in growing emerging companies focused on the development of under-utilized pharmaceutical compounds to meet unmet medical needs. We intend to use this experience to develop and ultimately commercialize cytisinicline either directly or via strategic collaborations.

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.

Non-clinical toxicology studies were sponsored by the National Center for Complementary and Integrative Health, or NCCIH, a division of the National Institutes of Health, or 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 United Sates Food and Drug Administration, or FDA.

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. The trial evaluated both 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.

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.

We presented the ORCA-1 results in September 2019 at the annual European meeting of the Society for Research on Nicotine and Tobacco, or SRNT, held in Oslo, Norway. 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 also discussed the trial's outcome with the FDA in November 2019 and finalized our Phase 3 protocol details and planning with the FDA.

We plan to initiate a Phase 3 trial in mid- 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.

We are also considering potential clinical studies in users of e-cigarettes. This is an important area of focus given the vaping epidemic and the number of vaping-related lung illnesses that were reported in 2019. 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 another 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 have engaged FreeMind Group to assist in conducting a strategic assessment and in securing non-dilutive funding to evaluate cytisinicline in reduction or cessation of vaping and or e-cigarettes.

Recent Corporate History

On May 23, 2018, we effected a one-for-ten reverse stock split on our shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto have been retroactively adjusted for the stock split as if such stock split occurred on the first day of the first period presented. Certain amounts in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

On August 1, 2017, OncoGenex Pharmaceuticals, Inc., or OncoGenex, completed a transaction, or the Arrangement, with Achieve Life Science, Inc., or Achieve, as contemplated by the Merger Agreement between Achieve and OncoGenex dated January 5, 2017, or the Merger Agreement. Under the terms of the Merger Agreement, OncoGenex instituted an one-for-eleven reverse stock split, issued 821,011 shares of its common stock (after accounting for the elimination of resulting fractional shares) in exchange for all of the outstanding preferred shares, common shares and convertible debentures of Achieve, and as a result Achieve became a wholly-owned subsidiary of OncoGenex. OncoGenex changed its name to Achieve Life Sciences, Inc., and is listed on the Nasdaq Capital Market under the ticker symbol ACHV. More information concerning the Arrangement is contained in our Current Report on Form 8-K filed on August 2, 2017 and our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC on June 6, 2017.

Our financial results account for the Arrangement between OncoGenex and Achieve as a reverse merger, whereby Achieve is deemed to be the acquiring entity from an accounting perspective. Our consolidated results of operations for the year ended December 31, 2017 include the results of operations of only Achieve for the time period of January 1, 2017 through August 1, 2017 and include the results of the combined company following the completion of the Arrangement on August 1, 2017. This treatment and presentation is in accordance with ASC 805, “Business Combinations”. Information relating to the number of shares, price per share and per share amounts of common stock are presented on a post- reverse stock split basis, as a reverse stock split in the ratio of one-for-eleven was effected in connection with the Arrangement.

OUR PRODUCT CANDIDATE - CYTISINICLINE

Overview of Cytisinicline

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 of Over-the-Counter, or 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 nicotine replacement therapies, or 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 United States and subsequently to other countries outside of Sopharma’s territory.

Non-clinical toxicology studies were sponsored by the NCCIH and by the NCI to assist in our 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 FDA 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 company sponsored studies. One of the chronic toxicology studies has been completed and submitted to the 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 a 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 been agreed that further escalation beyond the single 30.0 mg dose is not required. This Phase-1 study was 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 Program that aims to evaluate the effectiveness of cytisinicline for smoking cessation, nicotine addiction therapy, and potential benefit in other indications.

ORCA-1 was initiated in October 2018 and evaluated 254 smokers in the United States. The trial evaluated both 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.

We presented the ORCA-1 results in September 2019 at the annual European meeting of the SRNT held in Oslo, Norway. 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.

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 mid-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.

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	Cytisinicline (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	Cytisinicline (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 cytisinicline 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 adverse events excludes signs and symptoms of cold and influenza. Adverse events 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. The trial evaluated both 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 exists for cytisinicline. A recent periodic safety update report for the period of 2015 - 2020 submitted to the European authorities by Sopharma did not show any new safety signals with cytisinicline and there were no changes in expected benefit/risk during the specified period.

OVERVIEW OF MARKET AND TREATMENT

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 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 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 NRTs, 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 $1.1 billion in 2019. Of those sales, $899 million, approximately 82%, were attributable to the U.S. market.

The vast majority of 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.

LICENSE & SUPPLY AGREEMENTS

Sopharma AD

In 2009 and 2010, we entered into a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma, AD, or Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries including Germany, France and Italy related to oral dosage forms of cytisinicline. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, the trademark Tabex in all territories—other than certain countries in Central and Eastern Europe, Scandinavia, North Africa, the Middle East and Central Asia, as well as Vietnam, where Sopharma or its affiliates and agents already market Tabex—in connection with the marketing, distribution and sale of products. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-teens percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. We have agreed to cooperate with Sopharma in the defense against any actual or threatened infringement claims with respect to Tabex. Sopharma has the right to terminate the Sopharma License Agreement upon the termination or expiration of the Sopharma Supply Agreement. The Sopharma License Agreement will also terminate under customary termination provisions including bankruptcy or insolvency and material breach. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

A cross-license exists between us and Sopharma whereby we grant to Sopharma rights to any patents or patent applications or other intellectual property rights filed by us in Sopharma territories.

On May 14, 2015, we and Sopharma entered into an amendment to the Sopharma License Agreement. Among other things, the amendment to the Sopharma License Agreement reduced the royalty payments payable by us to Sopharma from a percentage in the mid-teens to a percentage in the mid-single digits and extended the term of the Sopharma License Agreement until May 26, 2029.

On July 28, 2017, we and Sopharma entered into the amended and restated Sopharma Supply Agreement. Pursuant to the amended and restated Sopharma Supply Agreement, for territories as detailed in the licensing agreement, we will exclusively purchase all of our cytisinicline from Sopharma, and Sopharma agrees to exclusively supply all such cytisinicline requested by us, and we extended the term to 2037. In addition, we will have full access to the cytisinicline supply chain and Sopharma will manufacture sufficient cytisinicline to meet a forecast for a specified demand of cytisinicline for the five years commencing shortly after the commencement of the agreement, with the forecast to be updated regularly thereafter. Each of us and Sopharma may terminate the Sopharma Supply Agreement in the event of the other party's material breach or bankruptcy or insolvency.

University of Bristol

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives for use in smoking cessation, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level. Any patents issued in connection with these applications would be scheduled to expire on February 5, 2036 at the earliest.

In consideration of rights granted by the University of Bristol, we agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize product candidates subject to the University

of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement, we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we agreed to pay an initial amount of $37,500 upon the execution of the amended University of Bristol License Agreement, and additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the amended University of Bristol License Agreement, in addition to amounts under the original University of Bristol License Agreement of up to $3.2 million in the aggregate, tied to specific financing, development and commercialization milestones. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible, as provided in the original University of Bristol License Agreement, for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Up to December 31, 2019, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Unless otherwise terminated, the University of Bristol License Agreement will continue until the earlier of July 2036 or the expiration of the last patent claim subject to the University of Bristol License Agreement. We may terminate the University of Bristol License Agreement for convenience upon a specified number of days' prior notice to the University of Bristol. The University of Bristol License Agreement will terminate under customary termination provisions including bankruptcy or insolvency or its material breach of the agreement. Under the terms of the University of Bristol License Agreement, we had provided 100 grams of cytisinicline to the University of Bristol as an initial contribution.

Summary of Milestone Obligations by Product Candidate

The following table sets forth the milestones that we may be required to pay to third parties under the license agreements described above. As described above, we will also be required to pay certain revenue-based royalties with respect to our product candidate.

Milestone Obligations to Third Parties	Amount Payable
University of Bristol	Up to $4,837,500 (1)

(1) Payable in connection with specific financing, development and commercialization milestones.

GOVERNMENT REGULATIONS

We are heavily regulated in most of the countries in which we operate. In the United States, the principal regulating authority is the FDA. The FDA regulates the safety and efficacy of product candidates and research, quality, manufacturing processes, product approval and promotion, advertising and product labeling. In the EU, the European Medicines Agency, or EMA, and national regulatory agencies regulate the scientific evaluation, supervision and safety monitoring of product candidates, and over-see the procedures for approval of drugs for the EU and European Economic Area countries similar regulations exist in most other countries, and in many countries the government also regulates prices. Health authorities in many middle and lower income countries require marketing approval by a recognized regulatory authority, such as the FDA or EMA, before they begin to conduct their application review process and/or issue their final approval.

United States

We intend to focus initially on clinical development of cytisinicline in the United States. It is anticipated that cytisinicline tablets would receive a minimum five years of data exclusivity under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.

Before a new pharmaceutical product may be marketed in the United States, the FDA must approve an NDA, for a new drug. The steps required before the FDA will approve an NDA generally include non-clinical studies followed by multiple stages of clinical trials conducted by the trial sponsor; sponsor submission of the NDA application to the FDA for review; the FDA's review of the data to assess the drug's safety and effectiveness; and the FDA's inspection of the facilities where the product will be manufactured.

As a condition of product approval, the FDA may require a sponsor to conduct post-marketing clinical trials, known as Phase 4 trials, and surveillance programs to monitor the effect of the approved product. The FDA may limit further marketing of a product based on the results of these post-market trials and programs. Any modifications to a drug, including new indications or changes to labeling or

manufacturing processes or facilities, may require the submission and approval of a new or supplemental NDA before the modification can be implemented, which may require that we generate additional data or conduct additional non-clinical studies and clinical trials. Our ongoing manufacture and distribution of drugs is subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences associated with the product, and adherence to current Good Manufacturing Practices, or cGMPs, which regulate all aspects of the manufacturing process. We are also subject to numerous regulatory requirements relating to the advertising and promotion of drugs, including, but not limited to, standards and regulations for direct-to-consumer advertising. Failure to comply with the applicable regulatory requirements governing the manufacture and marketing of our products may subject us to administrative or judicial sanctions, including warning letters, product recalls or seizures, injunctions, fines, civil penalties and/or criminal prosecution.

Sales and Marketing. The marketing practices of U.S. pharmaceutical companies are generally subject to various federal and state healthcare laws that are intended to prevent fraud and abuse in the healthcare industry and protect the integrity of government healthcare programs. These laws include anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a biopharmaceutical or medical device company from soliciting, offering, receiving or paying any remuneration to generate business, including the purchase or prescription of a particular product. False claims laws generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third-party payors (including Medicare and Medicaid) that are false or fraudulent. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to any particular industry practices, including the marketing practices of pharmaceutical and medical device companies. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions and/or exclusion from federal healthcare programs (including Medicare and Medicaid). The U.S. federal government and various states have also enacted laws to regulate the sales and marketing practices of pharmaceutical or medical device companies. These laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require disclosure to the federal or state government and public of such interactions; and/or require the adoption of compliance standards or programs. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to penalties under the pertinent laws and regulations.

Pricing and Reimbursement. Pricing for our pharmaceutical products will depend in part on government regulation. We will likely be required to offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid Drug Rebate Program, the “federal ceiling price” drug pricing program, the 340B drug pricing program and the Medicare Part D Program. We will also be required to report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to penalties.

In the United States, Medicaid currently covers all smoking cessation products including Chantix and Zyban. In March 2010, the Patient Protection and Affordable Care Act, or ACA, as amended by the Healthcare and Education Reconciliation Act, or collectively, 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. Section 2502 of the ACA specifies that tobacco cessation medications will be removed from the list of optional medications and required for inclusion in states’ prescription drug benefit. On May 2, 2014 the Department of Health and Human Services, or HHS, provided guidance into insurance coverage policy that health plans would be in compliance if they cover, among other items, screening for tobacco use, individual, group and phone counseling, all FDA approved tobacco cessation medications (both prescription and OTC) when prescribed by a healthcare provider, at least two quit attempts per year, four sessions of counseling and 90 days of treatment, with no cost sharing (co-pay) required.

Government and private third-party payers routinely seek to manage utilization and control the costs of our products. For example, the majority of states use preferred drug lists to restrict access to certain pharmaceutical products under Medicaid. Given certain states’ current and potential ongoing fiscal crises, a growing number of states are considering a variety of cost-control strategies, including capitated managed care plans that typically contain cost by restricting access to certain treatments.

Healthcare Reform. The United States and state governments continue to propose and pass legislation designed to regulate the healthcare industry. In March 2010, the U.S. Congress enacted the ACA, which included changes that significantly affected the pharmaceutical industry, such as:

- increasing drug rebates paid to state Medicaid programs under the Medicaid Drug Rebate Program for brand name and generic prescription drugs and extending those rebates to Medicaid managed care;
- Requiring pharmaceutical manufacturers to provide discounts on brand name prescription drugs sold to Medicare beneficiaries whose prescription drug costs cause the beneficiaries to be subject to the Medicare Part D coverage gap; and

- Imposing an annual fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid.

The ACA includes provisions designed to increase the number of Americans covered by health insurance. Specifically, since 2014, the ACA has required most individuals to maintain health insurance coverage or potentially to pay a penalty for noncompliance and has offered states the option of expanding Medicaid coverage to additional individuals. Additionally, policy efforts designed specifically to reduce patient out-of-pocket costs for medicines could result in new mandatory rebates and discounts or other pricing restrictions. Adoption of other new legislation at the federal or state level could further affect demand for, or pricing of, our products.

On January 20, 2017, President Donald Trump issued an Executive Order to initiate the repeal of the Healthcare Reform Law and we expect that additional state and federal healthcare measures under the Trump administration will 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 our product candidates, 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 prescription drugs for smoking cessation, but not OTC treatments. If these provisions are repealed, in whole or in part, our business, financial condition or results of operations could be negatively affected.

Anti-Corruption. The Foreign Corrupt Practices Act of 1977, as amended, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws.

Outside the United States

We expect to encounter similar regulatory and legislative issues in most other countries in which we seek to develop and commercialize cytisinicline.

New Drug Approvals and Pharmacovigilance. In the EU, the approval of new drugs may be achieved using the Mutual Recognition Procedure, the Decentralized Procedure or the EU Centralized Procedure. These procedures apply in the EU member states, plus the EEA countries, Norway, Iceland and Liechtenstein. The use of these procedures generally provides a more rapid and consistent approval process across the EU and EEA than was the case when the approval processes were operating independently within each country.

In 2012, new pharmacovigilance legislation came into force in the EU. Key changes include the establishment of a new Pharmacovigilance Risk Assessment Committee within the EMA, with responsibility for reviewing and making recommendations on product safety issues for the EU authorities. It also introduces the possibility for regulators to require pharmaceutical companies to conduct post-authorization efficacy studies at the time of approval, or at any time afterwards in light of scientific developments. There are also additional requirements regarding adverse drug reaction reporting and additional monitoring of products. Outside developed markets such as the EU and Japan, pharmacovigilance requirements vary and are typically less extensive.

The U.K. ceased to be a member state of the EU on January 31, 2020 (commonly known as Brexit). Since a significant portion of the regulatory framework in the U.K. is derived from the regulations of the EU, Brexit could materially change the regulatory framework applicable to the approval of our product candidates and other aspects of our business in the U.K., such as the pricing and importation of prescription products. However, at this time it is not known what new regulatory framework will be in place to govern the review and approval of new medicines in the U.K. The EMA was located in the U.K., but was fully relocated to Amsterdam in March 2020.

Health authorities in many middle and lower income countries require marketing approval by a recognized regulatory authority (i.e., similar to the authority of the FDA or the EMA) before they begin to conduct their application review process and/or issue their final approval. Many authorities also require local clinical data in the country’s population in order to receive final marketing approval. These requirements delay marketing authorization in those countries relative to the United States and Europe.

CONTRACT RESEARCH AGREEMENTS

Our strategy is to outsource certain product development activities and have established contract research agreements for, non-clinical, clinical, manufacturing and some data management services. We choose which business or institution to use for these services based on their expertise, capacity and reputation and the cost of the service.

We also provide or have provided quantities of our product candidates to academic research institutions to investigate the mechanism of action and evaluate novel combinations of product candidates with other cancer therapies in various cancer indications. These collaborations expand our research activities for our product candidates with modest contribution from us.

MANUFACTURING

We do not own or operate manufacturing facilities for the production of cytisinicline, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on Sopharma as supplier and contract manufacturer for all of our required raw materials, active pharmaceutical ingredients and finished drug product for our clinical trials. In addition to our Sopharma relationship, we utilize contract manufacturing organizations for the clinical packaging supplies of cytisinicline. We currently employ internal resources and third-party consultants to manage our clinical manufacturing activities.

Sopharma sources cytisinicline from the *Laburnum anagyroides* plant, a shrub or small tree native to, and widely distributed throughout, Bulgaria, south Central Europe and the northwestern Balkan Peninsula. The seed pods are harvested from the shrubs and dried. 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 five years to reach maturity for harvesting and has a productive life expectancy of 20 to 25 years. Seeds are harvested annually, dried and stored for processing into cytisinicline. *Laburnum* seeds in their natural state are highly toxic and the extraction process removes the toxins to produce highly purified cytisinicline. Sopharma is stockpiling *Laburnum* seeds to meet the projected demand from us upon commercial launch.

The active pharmaceutical ingredient, or API, manufacturing process utilizes a series of techniques including milling, solvent extraction, filtration and purification. Critical control steps and manufacturing intermediates have been identified and are controlled by internally developed specifications and methods to ensure a consistent and reproducible process. The highly purified cytisinicline is dried, sieved and packed for storage until further processing into drug product. The cytisinicline API manufacturing process has been developed and refined over many years of manufacture by Sopharma, which has significant expertise in manufacturing cytisinicline.

Sopharma manufactures cytisinicline API in its facilities in Bulgaria, which are near the capital, Sofia. The API processing facility complies with EU cGMP requirements and has been inspected by the Bulgarian Drug Agency.

SALES AND MARKETING

Our commercial strategy may include the use of strategic partners, distributors, a contract sale force or the establishment of our own commercial and specialty sales force. We plan to further evaluate these alternatives. We intend to seek partners in territories where we have no commercial experience and intend to directly market in niche markets where a small cost-effective commercial capability can generate direct revenues.

INTELLECTUAL PROPERTY

The U.S. Supreme Court has held that certain claims to naturally-occurring substances are not patentable. Cytisinicline is a naturally-occurring product and is therefore not patentable in the United States. Furthermore, cytisinicline has been in use in other parts of the world for decades, and is not susceptible to patenting in its current form.

Our development and commercialization of cytisinicline is protected by our exclusive supply agreement with Sopharma and Sopharma’s proprietary technology, experience and expertise in cytisinicline extraction. In addition, we intend to utilize market exclusivity laws including those under the Hatch-Waxman Act in the United States and exclusivity under Directive 2004/27/EC in the EU.

Additionally, we are actively building an intellectual property portfolio around our clinical-stage product candidate and research programs. A key component of this portfolio strategy is to seek international patent protection with patent applications in the United States and in major market countries that we consider important to the development of our business worldwide. As of December 31, 2019, we had a portfolio of three patent families being prosecuted in Australia, Canada, China, Europe including the U.K., Japan, S.

Korea, and the United States. One patent family is also filed in Mexico, New Zealand, South Africa. We have granted patents in the US, Canada, the UK, and South Africa. The patent portfolio includes compositions of matter and methods of use and synthesis for novel cytisinicline derivatives. We have filed one method of treatment patent application in the US, and may file in other jurisdictions in which methods of treatment are patentable in 2020. We have additionally acquired rights to a new method of cytisinicline extraction from Sopharma.

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights. A comprehensive discussion on risks relating to intellectual property is provided under “Risk Factors—Risks Related to Our Intellectual Property.”

In addition to patent protection, we rely on trade secrets, trademark protection and know-how to expand our proprietary position around our chemistry, technology and other discoveries and inventions that we consider important to our business. We also seek to protect our intellectual property in part by entering into confidentiality agreements with our employees, consultants, scientific advisors, clinical investigators and other contractors and also by requiring our employees, commercial contractors and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them.

COMPETITION

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 smoking cessation and other product candidates that it 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, Johnson & Johnson, Pharmacia Polanica, 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. We expect that our competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products in order to take advantage of the significant market opportunity.

Prescription Treatments

Two oral prescription drugs for smoking cessation are currently available in the United States. – Chantix and Zyban. Both have been proven effective in aiding smoking cessation, however, each is associated with a number of adverse effects.

We believe that cytisinicline may have similar efficacy to Chantix with potential fewer adverse events. A Cochrane Group independent database review of nicotine receptor partial agonists published in 2016, or the Cochrane Report, compared cytisinicline with Chantix and found no apparent difference in efficacy between cytisinicline and Chantix, in that the database review found that the risk ratio for cytisinicline and Chantix was in the same order of magnitude. In addition, it should be noted that only two studies were used to calculate the risk ratio for cytisinicline versus 27 trials for varenicline, and that evidence for varenicline was considered of high and moderate quality while the evidence for cytisinicline was considered low quality. However, a head-to-head comparative trial of these two treatments has not been performed. Furthermore, a report by the National Institute of Health Research in the U.K. comparing Chantix and cytisinicline concluded that cytisinicline appears to be more clinically effective and cost effective than varenicline (Chantix) based on expected costs and quality-adjusted life-year, or QALY, values.

The Cochrane Report researchers searched for randomized controlled trials testing varenicline, cytisinicline or dianicline, finding 39 studies of varenicline compared to placebo, bupropion or nicotine patches. The Cochrane Report researchers also found four trials of cytisinicline, one of which compared it to nicotine replacement therapy. The Cochrane Report also included one trial of dianicline, which is no longer in development, and so not available to use as a smoking cessation aid. To be included, trials had to report quit rates at least six months from the start of treatment. The Cochrane Report preferred the strictest available definition of quitting, and focused on results which had been biochemically confirmed by testing blood or bodily fluids. The Cochrane Report researchers conducted full searches up to May 2015, although several key trials published after that date were also included. The first cytisinicline trial included in the Cochrane Report was conducted in 1971. Since there are only two phase 3 studies with cytisinicline, the researchers that conducted the meta-analysis included in the Cochrane report determined that their meta-analysis was of poor quality.

Over-the-Counter Treatments

The most common OTC treatments bought in pharmacies for smoking cessation in the United States and worldwide are NRTs such as nicotine gums, nicotine lozenges, and nicotine patches. Each of these products delivers nicotine to the body although they generally do so at different rates and to different parts of the body than does a traditional cigarette. As concluded by the authors of several published clinical trials conducted by others, these therapies are generally less effective than prescription treatments. Recognized brands include Niquitin ® , Nicotinell ® , Nicorette ® and Nicoderm ® . Depending on the duration of treatment, the average cost of certain OTC smoking cessation treatments can exceed prescription treatments.

Pharmaceutical companies, including larger companies in the industry, who have extensive expertise in non-clinical and clinical testing and in obtaining regulatory approvals for products, may develop other OTC treatments for smoking cessation. 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.

EMPLOYEES

As of December 31, 2019, we had a total of 14 employees, of whom six were engaged in research and development functions, including clinical development, regulatory affairs and manufacturing, and eight were engaged in general and administrative functions, including accounting and finance, administration, and corporate communications.

All of our employees have entered into non-disclosure agreements regarding our intellectual property, trade secrets and other confidential information. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that we maintain satisfactory relations with our employees.

From time to time, we also use outside consultants to provide advice on our clinical development plans, research programs, administration and potential acquisitions of new technologies.

COMPANY INFORMATION

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, we completed the Arrangement, in connection with whichwe changed our name to Achieve Life Sciences, Inc. As a result of the Arrangement, Achieve became our wholly owned subsidiary. Extab Corporation, a Delaware corporation, which was formed in 2009 became a wholly-owned subsidiary of Achieve Life Sciences. Extab Corporation in turn has one direct wholly-owned subsidiary, Achieve Pharma U.K. Limited, a U.K. company, which was formed in 2009. As used in this Annual Report on Form 10-K, the term “OncoGenex” refers to our business prior to August 1, 2017.

AVAILABLE INFORMATION

We maintain a website at http://www.achievelifesciences.com. The information contained on or accessible through our website is not part of this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such reports with, or furnish those reports to, the SEC. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K and in the other periodic and current reports and other documents we file with the Securities and Exchange Commission, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment. This list is not exhaustive and the order of presentation does not reflect management's determination of priority or likelihood.

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, non-dilutive fundraising 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 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 U.S. 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 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 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 ceased to be a member state of the European Union on January 31, 2020 (commonly known as Brexit). 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.

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 e-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. We have engaged FreeMind Group to assist in conducting a strategic assessment and securing non-dilutive funding to evaluatate cytisinicline in vaping and e-cigartettes. FreeMind Group and other advisors may not be successful in securing non-dilutive funding, and we may ultimately abandon our efforts to expand into e-cigarette and vaping indications if we are unable to obtain funding or we believe the strategic assessment of such expansion is unfavorable.

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.

Our business is subject to risks arising from epidemic diseases, such as the recent outbreak of the COVID-19 illness.

The recent outbreak in China of the Coronavirus Disease 2019, or COVID-19, which has been declared by the World Health Organization to be a "public health emergency of international concern," has spread across the globe and is impacting worldwide economic activity. A public health epidemic, including COVID-19, poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for clinical trials and adversely impact our business, financial condition or results of operations. The COVID-19 outbreak and mitigation measures may also have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact

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 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, Johnson & Johnson, 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 EMA, 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. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

The price for our common stock is volatile.

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

- our ability to raise additional capital, the terms of such capital, and our ability to continue as a going concern;
- the ability of us or our partners to develop cytisinicline and other product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of us or our partners to obtain regulatory approvals for cytisinicline or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;

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

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

The price of our common stock does not meet the requirements for continued listing on The NASDAQ Capital Market. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of The NASDAQ Capital Market require, among other things, that the minimum bid price of a listed company's stock be at or above $1.00. If the minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with The NASDAQ Capital Market's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. As previously reported, on January 4, 2020, we received a notice from the NASDAQ Listing Qualifications Department notifying us that for 30 consecutive trading days, the bid price of our common stock had closed below the minimum $1.00 per share requirement. In accordance with The NASDAQ Capital Market's listing rules, we were afforded 180 calendar days, or until July 22, 2020, to regain compliance with the bid price requirement. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

If we fail to regain compliance, our common stock will be subject to delisting. Delisting from The NASDAQ Capital Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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, which was amended in March 2020, pursuant to which 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 approximately $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 54-month term of the Purchase Agreement in increments of up to 150,000 shares of common stock. 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.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We have business offices located in Seattle, Washington and Vancouver, British Columbia.

Our lease agreement for office space in Seattle, Washington commenced on March 1, 2018 and has a three-year term. Pursuant to this lease, we rent approximately 3,187 square feet of office space. The annual rent is approximately $0.1 million.

We leased approximately 4,857 square feet in Vancouver, British Columbia, at an annual rent of approximately $0.1 million, which expired on January 31, 2019. On November 19, 2018, we entered into a lease agreement for new office space in Vancouver, British Columbia, which commenced on February 1, 2019, and has a four-year term. Pursuant to this lease, we rent approximately 2,367 square feet of office space. The annual rent is approximately $0.1 million.

We believe that the facilities we currently lease are sufficient for our anticipated near-term needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are not currently a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on the results of our operations or financial position. There are no material proceedings to which any director, officer or any of our affiliates, any owner of record or beneficially of more than five percent of any class of our voting securities, or any associate of any such director, officer, our affiliates, or security holder, is a party adverse to us or our consolidated subsidiary or has a material interest adverse thereto.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock first began trading on the Nasdaq National Market under the symbol "SNUS" on October 12, 1995. In connection with a corporate transaction and name change, our common stock commenced trading on the Nasdaq Capital Market under the stock symbol "OGXI", effective August 21, 2008. Following the completion of the Arrangement discussed elsewhere in this Annual Report on Form 10-K, our common stock commenced trading on the Nasdaq Capital Market under the stock symbol "ACHV", effective August 2, 2017.

No cash dividends have been paid on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. As of February 18, 2020, there were approximately 16 stockholders of record and there were approximately 8,598 beneficial stockholders of our common stock.

The information required by this item regarding equity compensation plan information is set forth in Part III, Item 12 of this Annual Report on Form 10-K.

No purchases of equity securities during the year ended December 31, 2019 were made by us or on our behalf.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The data set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and Notes thereto appearing at Item 8 of this Annual Report on Form 10-K. The selected consolidated statements of loss data for the years ended December 31, 2019, 2018 and 2017 and consolidated balance sheet data as of December 31, 2019, 2018 and 2017 set forth below have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

In connection with the Arrangement, Achieve was considered to be the acquiring company for accounting purposes. Accordingly, the assets and liabilities of OncoGenex were recorded, as of the effective time of the Arrangement, at their respective fair values and added to those of Achieve. The results of the operations and balance sheet data for the year ended December 31, 2017 reflect the results of only Achieve for the time period of January 1, 2017 through August 1, 2017 and the results of the combined company from August 2, 2017 through December 31, 2017. The historical results presented are not necessarily indicative of future results.

	December 31,		
	2019	2018	2017
	(in thousands except share and per share amounts)		
Statements of Loss Data:			
Total expenses	$ 16,528	$ 12,813	$ 6,632
Net loss	$ (16,395)	$ (12,687)	$ (10,583)
Basic and diluted loss per common share	$ (1.99)	$ (3.61)	$ (22.07)
Shares used in calculation of net loss per share			
Basic and diluted	8,246,400	3,510,217	479,442

	December 31,		
	2019	2018	2017
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 16,664	$ 14,604	$ 5,284
Total assets	$ 21,078	$ 19,084	$ 9,892
Current liabilities	$ 2,869	$ 3,270	$ 2,013
Total liabilities	$ 3,028	$ 3,282	$ 2,013
Additional paid-in capital	$ 63,709	$ 41,161	$ 20,556
Accumulated deficit	$ (45,704)	$ (25,381)	$ (12,694)
Stockholders' equity	$ 18,050	$ 15,802	$ 7,879

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Annual Report on Form 10-K contains "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 Annual Report on Form 10-K or in documents incorporated by reference into this Annual Report on Form 10-K. 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 those discussed in Item 1A "Risk Factors," as well as those discussed elsewhere in the Annual Report on Form 10-K.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K 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 Annual Report on Form 10-K 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.

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.

Our management team has significant experience in growing emerging companies focused on the development of under-utilized pharmaceutical compounds to meet unmet medical needs. We intend to use this experience to develop and ultimately commercialize cytisinicline either directly or via strategic collaborations.

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.

Non-clinical toxicology studies were sponsored by the National Center for Complementary and Integrative Health, or NCCIH, a division of the National Institutes of Health, or 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 United Sates Food and Drug Administration, or 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 FDA 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 company 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 a 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 been agreed that further escalation beyond the single 30.0 mg dose is not required. This Phase-1 study was 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. The trial evaluated both 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.

We presented the ORCA-1 results in September 2019 at the annual European meeting of the Society for Research on Nicotine and Tobacco, or SRNT, held in Oslo, Norway. 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.

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 mid-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.

We are also considering potential clinical studies in users of e-cigarettes. This is an important area of focus given the vaping epidemic and the number of vaping-related lung illnesses that were reported in 2019. 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 another 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 have engaged FreeMind Group to assist in conducting a strategic assessment and in securing non-dilutive funding to evaluate cytisinicline in reduction or cessation of vaping and or e-cigarettes.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We have never been profitable and have incurred operating losses in each year since inception. Our net loss was $16.4 million and $12.7 million for the years ending December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $45.7 million, cash and cash equivalents balance of $16.7 million and a positive working capital balance of $14.5 million. During the year ended December 31, 2019, net cash used in operations was $15.2 million.

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 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. 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 occurs, our ability to achieve our development and commercialization goals would be adversely affected.

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 amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate.

Our accompanying financial results have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The financial results do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

Recent Corporate History

On May 23, 2018, we effected a one-for-ten reverse stock split on our shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto have been retroactively adjusted for the stock split as if such stock split occurred on the first day of the first period presented. Certain amounts in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

On August 1, 2017, OncoGenex Pharmaceuticals, Inc., or OncoGenex, completed a transaction, or the Arrangement, with Achieve Life Science, Inc., or Achieve, as contemplated by the Merger Agreement between Achieve and OncoGenex dated January 5, 2017, or the Merger Agreement. Under the terms of the Merger Agreement, OncoGenex changed its name to Achieve Life Sciences, Inc., instituted an one-for-eleven reverse stock split, issued 821,011 shares of its common stock (after accounting for the elimination of resulting fractional shares) in exchange for all of the outstanding preferred shares, common shares and convertible debentures of Achieve, and as a result Achieve became a wholly-owned subsidiary of OncoGenex, and is listed on the Nasdaq Capital Market under the ticker symbol ACHV. More information concerning the Arrangement is contained in our Current Report on Form 8-K filed on August 2, 2017 and our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC on June 6, 2017.

Our consolidated financial statements account for the Arrangement between OncoGenex and Achieve as a reverse merger, whereby Achieve is deemed to be the acquiring entity from an accounting perspective. Our consolidated results of operations for the year ended December 31, 2017 include the results of operations of only Achieve for the time period of January 1, 2017 through August 1, 2017 and include the results of the combined company following the completion of the Arrangement on August 1, 2017. This treatment and presentation is in accordance with ASC 805, “Business Combinations”. Information relating to the number of shares, price per share and per share amounts of common stock are presented on a post- reverse stock split basis, as a reverse stock split in the ratio of one-for-eleven was effected in connection with the Arrangement.

In connection with the Arrangement, OncoGenex issued contingent value rights, or CVRs, on July 31, 2017 to their existing stockholders as of July 27, 2017. One CVR was issued for each share of their common stock outstanding as of the record date for such issuance. The CVRs expired on August 17, 2017. A recovery of $0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss.

License & Supply Agreements

Sopharma License and Supply Agreements

We are party to a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma, AD, or Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries related to new oral dosage forms of cytisinicline providing enhanced stability. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, the trademark Tabex in all territories described in the Sopharma License Agreement. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-single digit percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

University of Bristol License Agreement

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level.

In consideration of rights granted by the University of Bristol, we paid a nominal license fee and agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize any product candidates subject to the University of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we agreed to pay an initial amount of $37,500 upon the execution of the amended University of Bristol License Agreement, and additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the amended University of Bristol License Agreement, in addition to amounts under the original University of Bristol License Agreement of up to $3.2 million in the aggregate, tied to specific financing, development and commercialization milestones. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible, as provided in the original University of Bristol License Agreement, for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Up to December 31, 2019, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for clinical trials, contract manufacturing, personnel costs, milestone payments to third parties, facilities, regulatory activities, non-clinical studies and allocations of other R&D-related costs. External expenses for clinical trials include fees paid to clinical research organizations, clinical trial site costs and patient treatment costs.

We manage our clinical trials through contract research organizations and independent medical investigators at our sites and at hospitals and expect this practice to continue. Due to our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs incurred for our research and development programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct our ongoing non-clinical studies, and initiate new clinical trials and registration-enabling activities. The process of conducting clinical trials and non-clinical studies necessary to obtain regulatory approval is costly and time consuming and we may never succeed in achieving marketing approval for cytisinicline. (See “Item 1A. Risk Factors—Risks Related to the Development of Our Product Candidate Cytisinicline.”)

Successful development of cytisinicline is highly uncertain and may not result in an approved product. We cannot estimate completion dates for development activities or when we might receive material net cash inflows from our R&D projects, if ever. We anticipate we will make determinations as to which markets, and therefore, which regulatory approvals, to pursue and how much funding to direct toward achieving regulatory approval in each market on an ongoing basis in response to our ability to enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, and ongoing assessments as to each future product candidate’s commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance its various programs.

Our projects or intended R&D activities may be subject to change from time to time as we evaluate results from completed studies, our R&D priorities and available resources.

General and Administrative Expenses

General and administrative, or G&A, expenses consist primarily of salaries and related costs for our personnel in executive, finance and accounting, corporate communications and other administrative functions, as well as consulting costs, including market research, business consulting, human resources and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs.

Results of Operations

Years Ended December 31, 2019, 2018 and 2017

Research and Development Expenses

Our research and development expenses for our clinical development programs were as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Clinical development programs:			
Cytisinicline	$ 9,674	$ 5,868	$ 1,590
Other research and development	—	—	1,511
Total research and development expenses	**$ 9,674**	**$ 5,868**	**$ 3,101**

Research and development expenses for the years ended December 31, 2019, 2018 and 2017 were $9.7 million, $5.9 million and $3.1 million, respectively. The increase in 2019 as compared to 2018 was primarily due to our ORCA-1 trial, a Phase 2b optimization study that was initiated in October 2018 and was completed in June 2019. The increase in 2018 as compared to 2017 was due to higher employee expenses from a full year of operation after the reverse merger with OncoGenex that occurred in August 2017, increased drug supply expenses for the initiation of the ORCA-1 trial, in October 2018 and increased research and development activity for our cytisinicline clinical development program, including costs associated with the ramp up of the repeat dose pharmacokinetics trial and toxicology studies initiated in late 2017.

General and Administrative Expenses

G&A expenses for the years ended December 31, 2019, 2018 and 2017 were $6.9 million, $6.9 million and $3.5 million, respectively. The increase in 2018 as compared to 2017 was due to higher employee and public company related expenses, including investor relations, directors' fees, insurance premiums and business tax and license fees, from a full year of operation after the reverse merger with OncoGenex that occurred in August 2017.

Gain on warrants

We revalue our warrants classified as derivative liabilities at each balance sheet date to fair value. As at December 31, 2019 we had no warrants classified as liabilities. We recorded no gain or loss on the revaluation of our outstanding warrants for the year ended December 31, 2018. For the year ended December 31, 2017 we recorded a gain on the revaluation of $0.1 million.

Bargain purchase gain

In accordance with ASC 805, "Business Combinations," the excess of fair value of acquired net assets over purchase price (negative goodwill) of $1.3 million, was recognized as a gain in the period the Arrangement was completed. We have reassessed whether all acquired assets and assumed liabilities have been identified and recognized and performed remeasurements to verify that the consideration paid, assets acquired, and liabilities assumed have been properly valued.

Contingent value rights recovery

The contingent value rights issued by Oncogenex to its shareholders prior to the closing of the Arrangement expired on August 17, 2017, as we did not enter into any term sheets or agreement with third parties for the development or commercialization of apatorsen. A recovery of $0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss in 2017.

Loss on disposition of intangible asset and recovery of deferred income taxes

In August 2017, we discontinued further development of apatorsen. We recognized a loss on disposition of apatorsen of $8.6 million and a deferred income tax recovery of $2.9 million as a result of discontinuing the development program and providing a notice of discontinuance of the license agreements with Ionis Pharmaceuticals, Inc.

Liquidity and Capital Resources

We incurred an accumulated deficit of $45.7 million through December 31, 2019, and we expect to incur substantial additional losses in the future as we operate our business and continue or expand our R&D activities and other operations. We have not generated any revenue from product sales to date, and we may not generate product sales revenue in the near future, if ever. As of December 31, 2019, we had a cash, cash equivalents and short-term investments balance of $16.7 million and a positive working capital balance of $14.5 million.

The financial results have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business.

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. There is no assurance that we will obtain financing from other sources. We have, thus far, financed our operations through payments from former collaborators and equity financings. 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. 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 amount and timing of our future funding requirements will depend on

many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate.

The consolidated financial results do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

Lincoln Park Capital Equity Line

On September 14, 2017, we and Lincoln Park Capital Fund, LLC, or LPC, entered into a share and unit purchase agreement, which was amended on March 12, 2020, or the Purchase Agreement, pursuant to which we have the right to sell to LPC up to $11.0 million in shares of our common stock, par value $0.001 per share, subject to certain limitations and conditions set forth in the Purchase Agreement. On May 22, 2018 we obtained the requisite stockholder authorization to sell shares of our common stock to LPC in excess of 20% of our outstanding shares of common stock (as of the date we entered into the purchase agreement) in order to be able to sell to LPC the full amount remaining under the Purchase Agreement.

Pursuant to the Purchase Agreement, LPC initially purchased 32,895 of our units, or the Units, at a purchase price of $30.40 per Unit, with each Unit consisting of (a) one share of our Common Stock and (b) one warrant to purchase one-quarter of a share of Common Stock at an exercise price of $34.96 per share, or Warrant. Each Warrant became exercisable six months following the issuance date until the date that is five years and six months after the issuance date and is subject to customary adjustments. The Warrants were issued only as part of the Units in the initial purchase of $1.0 million and no warrants shall be issued in connection with any other purchases of common stock under the Purchase Agreement.

After the initial purchase, as often as every other business day over the 54-month term of the Purchase Agreement, and up to an aggregate amount of an additional approximately $10.0 million (subject to certain limitations) of shares of common stock, we have the right, from time to time, in our sole discretion and subject to certain conditions to direct LPC to purchase up to 150,000 shares of common stock. The purchase price of shares of common stock pursuant to the Purchase Agreement will be based on prevailing market prices of common stock at the time of sales without any fixed discount, and we will control the timing and amount of any sales of common stock to LPC. In addition, we may direct LPC to purchase additional amounts as accelerated purchases as described in the Purchase Agreement. As consideration for entering into the Purchase Agreement, we issued to LPC 12,352 shares of common stock in September 2017 and, in connection with the amendment of the Purchase Agreement in March 2020, we agreed to pay to LPC $0.1 million as an expense reimbursement. The consideration of 12,352 shares of our common stock were fair valued based on the closing price of our common stock as at the transaction date and recognized as part of offering expenses.

From September 14, 2017 through March 13, 2020, we offered and sold 557,378 shares of our common stock pursuant to our Purchase Agreement with LPC, including the 32,895 shares that were part of the initial purchase of Units. These sales resulted in gross proceeds to us of approximately $4.4 million and offering expenses of $0.5 million.

June 2018 Public Offering

On June 19, 2018, we completed an underwritten registered public offering, pursuant to which we sold 710,500 Class A Units at a price per unit of $4.00 and 9,158 Class B Units at a price per unit of $1,000.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series A Convertible Preferred Stock convertible at any time at the holder’s option into 250 shares of common stock, and warrants to purchase 250 shares of common stock.

Each warrant was immediately exercisable, expires on the five-year anniversary of the date of issuance and is exercisable at a price per share of common stock of $4.00. Additionally, subject to certain exceptions, if, after the June 19, 2018, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the 2018 Measurement Period, which 2018 Measurement Period commences on June 19, 2018, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such 2018 Measurement Period exceeds $500,000 per trading day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then we may call for cancellation of all or any portion of the warrants then outstanding.

The Class A Units and Class B Units were not certificated and the shares of common stock, Series A Convertible preferred stock and warrants comprising such Units were immediately separable and were issued separately in the public offering. The Class A and B Units were offered by us pursuant to the registration statement on Form S-1 (File No. 333-224840), and each amendment thereto, which was initially filed with the SEC, on May 10, 2018 and declared effective by the SEC on June 14, 2018, and the registration statement on Form S-1 (File No. 333- 225649) filed by the us with the SEC pursuant to Rule 462(b) of the Securities Act of 1933 on June 14, 2018.

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or the Underwriter, on June 15, 2018, we granted the Underwriter a 45 day option, or the 2018 Overallotment Option, to purchase up to 450,000 additional shares of common stock and/or warrants to purchase up to 450,000 shares of Common Stock solely to cover over-allotments. The 2018 Overallotment Option was exercised in full on June 18, 2018.

We received net proceeds of approximately $12.2 million, after deducting underwriting discounts and commissions and offering expenses.

As of March 13, 2020, all 9,158 shares of the Series A Convertible Preferred Stock had been converted into 2,289,500 shares of common stock, and no shares of the Series A Convertible Preferred Stock remained outstanding.

From June 19, 2018 through March 13, 2020, 1,168,000 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of approximately $4.7 million, and as of March 13, 2020, 2,282,000 warrants remained outstanding.

October 2018 Registered Direct Offering

On October 3, 2018, we completed a registered direct offering, pursuant to which we sold 1,789,258 shares of common stock at a price of $3.1445. We also issued to the investors in a concurrent private placement unregistered warrants to purchase up to 0.5 shares of common stock for each share purchased in the registered direct offering, with an exercise price of $3.1445 per share. The warrants were exercisable immediately upon issuance and will expire five years following the date of issuance.

The registered direct offering raised total gross proceeds of $5.6 million and after deducting approximately $0.6 million in placement agent fees and offering expenses, we received net proceeds of $5.0 million.

At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On June 7, 2019, we entered into an At The Market Offering Agreement, or the Offering Agreement, with H.C. Wainwright & Co., LLC, as agent, or H.C. Wainwright, pursuant to which we may offer and sell, from time to time and at our election, through H.C. Wainwright, shares of our common stock having an aggregate offering price of up to $6.0 million.

Pursuant to 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. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares of common stock from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

We will pay H.C. Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of shares of common stock and have agreed to reimburse H.C. Wainwright for certain specified expenses in connection with entering into the Offering Agreement.

From June 7, 2019 to March 13, 2020, we did not offer any shares of our common stock for sale pursuant to the Offering Agreement. As of March 13, 2020, shares of our common stock having an aggregate value of approximately $6.0 million remained available for sale under the Offering Agreement.

Warrant Exercise Agreement

On May 30, 2019, we entered into a Warrant Exercise Agreement, or the Exercise Agreement, with Armistice Capital Master Fund, Ltd., or Armistice. Pursuant to the Exercise Agreement, Armistice exercised (i) outstanding warrants to purchase 270,313 shares of our common stock with an exercise price of $3.1445 per share issued as part of the October 2018 financing and (ii) outstanding warrants to purchase 837,500 shares of our common stock with an exercise price of $4.00 per share issued as part of the June 2018 financing, for aggregate exercise proceeds to us of approximately $4.2 million, or, collectively, the Warrant Exercise.

As an inducement for the Warrant Exercise, we agreed to issue to Armistice a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of our common stock at an exercise price of $4.50 per share, or the New Warrant. We also agreed to file a registration statement covering the resale of the shares underlying the New Warrant. The New Warrant and the shares underlying the New Warrant were offered to Armistice in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act.

Under ASC 260, the fair value of the New Warrant of $3.9 million was recognized into accumulated deficit.

December 2019 Public Offering

On December 17, 2019, we completed an underwritten registered public offering, pursuant to which we sold 9,577,504 Class A Units at a price per unit of $0.60 and 6,256 Class B Units at a price per unit of $999.60.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series B Convertible Preferred Stock, par value $0.001 per share, convertible at any time at the holder's option into 1,666 shares of common stock, and warrants to purchase 1,666 shares of common stock.

Each warrant was immediately exercisable, expires on the five year anniversary of the date of issuance and is exercisable at a price per share of common stock of $0.60, subject to adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect, provided, however, that the exercise price of the warrants cannot be reduced to an amount less than $0.06 per share of common stock. Additionally, subject to certain exceptions, if, after December 17, 2019, (i) the volume weighted average price of the common stock for each of 30 consecutive trading days, or the 2019 Measurement Period, which 2019 Measurement Period commences on the closing date, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such 2019 Measurement Period exceeds $500,000 per trading day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then the Company may call for cancellation of all or any portion of the warrants then outstanding.

The Class A Units and Class B Units were not certificated and the shares of common stock, Series B Convertible Preferred Stock and warrants comprising such Units were immediately separable and were issued separately in the public offering. The Class A and B Units were offered by us pursuant to the registration statement on Form S-1 (File No. 333-234530), and each amendment thereto, which was initially filed with the SEC on November 6, 2019 and declared effective by the SEC on December 17, 2019.

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or Ladenburg, on December 17, 2019, we granted Ladenburg a 45 day option, or the 2019 Overallotment Option, to purchase up to 3,000,000 additional shares of Common Stock and/or Warrants to purchase up to 3,000,000 shares of Common Stock solely to cover over-allotments. The 2019 Overallotment Option was exercised in full on December 17, 2019.

The public offering raised total gross proceeds of $13.8 million and after deducting $1.5 million in underwriting discounts and commissions and offering expenses, we received net proceeds of $12.3 million.

The underwriting discounts and commissions and offering expenses have been charged against the gross proceeds.

As of March 13, 2020, 5,793 shares of the Series B Convertible Preferred Stock had been converted into 9,651,138 shares of common stock, and 463 shares of the Series B Convertible Preferred Stock remained outstanding.

As of March 13, 2020, no warrants issued in the December 2019 financing had been exercised.

Cash Flows

Operating Activities

For the years ended December 31, 2019, 2018 and 2017, net cash used in operating activities was $15.2 million, $10.6 million, and $9.1 million, respectively. The increase in cash used in operations in 2019 as compared to 2018 was primarily attributable to increased research and development expenses related to our ORCA-1 trial. The increase in cash used in operations in 2018 as compared to 2017 was due to a full year of operation after the reverse merger with OncoGenex that occurred in August 2017 and upfront payments made to the CRO for the initiation of the ORCA-1 trial.

Financing Activities

For the years ended December 31, 2019, 2018 and 2017 net cash provided by financing activities was $17.3 million, $19.8 million and $2.0 million, respectively. Net cash provided by financing activities for the year ended December 31, 2019 relates to proceeds from our December 2019 public offering, from warrant exercises and from our purchase agreement with LPC. Net cash provided by financing activities for the year ended December 31, 2018 relates to proceeds from our June 2018 public offering, October 2018 registered direct offering and exercise of warrants. Net cash provided by financing activities for the year ended December 31, 2017 related to proceeds received from our purchase agreement with LPC.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 was $5.0 million. Net cash used in investing activities for the year ended December 31, 2018 was $5.1 million. Net cash provided by investing activities for the year ended December 31, 2017 was $12.6 million. Net cash used in investing activities for the years ended December 31, 2019 and 2018 were due mainly to transactions involving short-term investments in the normal course of business. Net cash provided by investing activities for the year ended December 31, 2017 was due to the reverse merger with OncoGenex.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Seattle office operating lease (1)	$ 173	$ 148	$ 25	$ —	$ —
Vancouver office operating lease (2)	$ 204	$ 65	$ 133	$ 6	$ —
Total	$ 377	$ 213	$ 158	$ 6	$ —

(1) This operating lease is effective March 1, 2018 and expires on February 28, 2021.
(2) This operating lease is effective February 1, 2019 and expires on January 31, 2023.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet financing arrangements at December 31, 2019.

Inflation

We do not believe that inflation has had a material effect on our business and results of operations during the periods presented.

Material Changes in Financial Condition

	December 31,	
(in thousands)	2019	2018
Total Assets	$ 21,078	$ 19,084
Total Liabilities	3,028	3,282
Total Equity	18,050	15,802

The increase in assets as at December 31, 2019 as compared to December 31, 2018 primarily relates to increase in cash and cash equivalents from the December 2019 public offering, warrant exercises and from our purchase agreement with LPC. The decrease in liabilities as at December 31, 2019 compared to December 31, 2018 was primarily due to lower clinical trial accruals associated with completion of our ORCA-1 trial in June 2019.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and notes thereto. Actual results could differ from these estimates. Estimates and assumptions principally relate to estimates of the fair value of our warrant liability, the initial fair value and forfeiture rates of stock options issued to employees and consultants, the estimated compensation cost on performance restricted stock unit awards, clinical trial and manufacturing accruals, estimated useful lives of property, plant, equipment and intangible assets, estimates and assumptions in contingent liabilities.

Fair value of financial instruments

The fair value of our cash equivalents and marketable securities is based on quoted market prices and trade data for comparable securities. We determine the fair value of our warrant liability based on the Black-Scholes pricing model and using considerable judgment, including estimating stock price volatility and expected warrant life. Other financial instruments including amounts

receivable, accounts payable, accrued liabilities other, accrued clinical liabilities and accrued compensation are carried at cost, which we believe approximates fair value because of the short-term maturities of these instruments.

Intangible Assets

Our intangible assets are subject to amortization and are amortized using the straight-line method over their estimated period of benefit. We evaluate the carrying amount of intangible assets periodically by taking into account events or circumstances that may warrant revised estimates of useful lives or that indicate the asset may be impaired.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. We conduct our long-lived asset impairment analyses in accordance with ASC 360-10-15, "Impairment or Disposal of Long-Lived Assets." ASC 360-10-15 requires us to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

Goodwill

Goodwill acquired in a business combination is assigned to the reporting unit that is expected to benefit from the combination as of the acquisition date. Goodwill is tested for impairment on an annual basis or, more frequently, if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the carrying values of assets and liabilities and their respective income tax bases and for operating losses and tax credit carry forwards. A valuation allowance is provided for the portion of deferred tax assets that is more likely than not to be unrealized. Deferred tax assets and liabilities are measured using the enacted tax rates and laws.

Research and Development Costs

Research and development costs are expensed as incurred, net of related refundable investment tax credits, with the exception of non-refundable advance payments for goods or services to be used in future research and development, which are capitalized in accordance with ASC 730, "Research and Development" and included within Prepaid Expenses or Other Assets depending on when the assets will be utilized.

Clinical trial expenses are a component of research and development costs. These expenses include fees paid to contract research organizations and investigators and other service providers, which conduct certain product development activities on our behalf. We use an accrual basis of accounting, based upon estimates of the amount of service completed. In the event payments differ from the amount of service completed, prepaid expense or accrued liabilities amounts are adjusted on the balance sheet. These expenses are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. We monitor each of these factors to the extent possible and adjust estimates accordingly.

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of the ASC 718, "Stock Compensation", using the modified prospective method with respect to options granted to employees and directors. The expense is amortized on a straight-line basis over the graded vesting period.

Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four-year period. We also granted restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, we evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance provision or the occurrence of other events that may have caused the awards to accelerate and vest.

Segment Information

We follow the requirements of ASC 280, “Segment Reporting.” We have one operating segment, dedicated to the development and commercialization of cytisinicline for smoking cessation, with operations located in Canada and the U.S.

Warrants

We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company’s own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of registered securities upon exercise and therefore do not sufficiently preclude an implied right to net cash settlement. We classify warrants on the consolidated balance sheet as a liability which is revalued at each balance sheet date subsequent to the initial issuance. We also have warrants classified as equity and these are not reassessed for their fair value at the end of each reporting period. Warrants classified as equity are initially measured at their fair value and recognized as part of stockholders’ equity. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the warrants. Changes in the fair value of the warrants classified as liabilities are reflected in the consolidated statement of loss as gain (loss) on revaluation of warrants.

Reporting Currency and Foreign Currency Translation

Effective August 2, 2017, we changed the functional currency of our U.K. subsidiary from the Great British Pound to the U.S. dollar. As a result of the Arrangement, the U.K. subsidiary’s primary economic environment has now changed from the U.K. to the U.S. This has resulted in significant changes in economic facts and circumstances that clearly indicate that the functional currency has changed. We accounted for the change in functional currency prospectively.

The consolidated financial statements for the period of January 1, 2017 to August 2, 2017, are based on the U.K. subsidiary with a functional currency of GBP, and have been translated into the U.S. reporting currency using the current rate method as required by SFAS No. 52, “Foreign Currency Translation”, or SFAS 52, as follows: assets and liabilities using the rate of exchange prevailing at the balance sheet date; stockholders’ deficiency using the applicable historic rate; and revenue and expenses using the monthly average rate of exchange. Translation adjustments have been included as part of the accumulated other comprehensive income

Our functional and reporting currency is the U.S. dollar. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates.

The functional currency of our foreign subsidiary is the U.S. dollar. For this foreign operation, assets and liabilities denominated in other than U.S. dollars are translated at the period-end rates for monetary assets and liabilities and historical rates for non-monetary assets and liabilities. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates. Gains and losses from this translation are recognized in the consolidated statement of loss.

Recently Adopted Accounting Policies

In May 2014, the Financial Accounting Standards Board, or FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606): Revenue from Contracts with Customers, which guidance in this update will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance when it becomes effective. ASU No. 2014-09 affects any entity that enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principal of ASU No. 2014-09 is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which will be our fiscal year 2018 (or December 31, 2018), and entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Early adoption is permitted. We have updated our policies and procedures to reflect the adoption of ASU No. 2014-09. The adoption of this standard did not have an impact on our financial position or results of operations.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards

as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. For public business entities, the amendments in this Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In February 2016, the FASB established Topic 842, Leases, by issuing Accounting Standards Update ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use, or ROU, model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases were classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of loss and comprehensive loss.

We adopted the standard on the effective date of January 1, 2019 and elected to use the modified retrospective method. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also elected the available practical expedients and implemented internal controls to enable the preparation of financial information on adoption.

The standard had a material impact on our consolidated balance sheets, but did not have an impact on our consolidated statements of loss and comprehensive loss. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases, while our accounting for finance leases remained substantially unchanged.

In August 2018, the FASB issued Accounting Standards Update 2018-13, Fair Value Measurement, which both modifies and clarifies the disclosure requirements for fair value measurement. This update is effective for financial statements issued for fiscal years beginning after December 15, 2019, with early adoption permitted. The adoption of this standard did not have a significant impact on our financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Achieve Life Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Achieve Life Sciences, Inc. and its subsidiaries (together, the Company) as of December 31, 2019 and 2018, and the related consolidated statements of loss and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and their results of operations and their cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America (US GAAP).

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP (signed)

Chartered Professional Accountants
Vancouver, Canada
March 13, 2020

We have served as the Company's auditor since 2017.

Achieve Life Sciences, Inc.

Consolidated Balance Sheets

(In thousands, except per share and share amounts)

	December 31, 2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents *[note 7]*	$ 16,664	$ 9,515
Short-term investments *[note 7]*	—	5,089
Amounts receivable	8	7
Prepaid expenses	662	926
Total current assets	**17,334**	**15,537**
Restricted cash *[note 7]*	50	50
Property and equipment, net *[note 8]*	57	35
Right-of-use assets *[note 13]*	329	—
Other assets *[note 9]*	187	118
License agreement *[note 2, 5 and 6]*	2,087	2,310
Goodwill *[note 2]*	1,034	1,034
Total assets	**$ 21,078**	**$ 19,084**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 859	$ 144
Accrued liabilities other	304	748
Accrued clinical liabilities	387	1,199
Accrued compensation	1,116	1,168
Current portion of long-term obligations *[note 13]*	203	11
Total current liabilities	**2,869**	**3,270**
Long-term obligations *[note 13]*	159	12
Total liabilities	**3,028**	**3,282**
Commitments and contingencies *[note 13]*		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value, 9,158 shares designated, zero issued and outstanding at December 31, 2019 and 579 issued and outstanding at December 31, 2018.	—	—
Series B convertible preferred stock, $0.001 par value, 6,256 shares designated, 1,121 issued and outstanding at December 31, 2019 and zero issued and outstanding at December 31, 2018.	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized, 29,485,178 and 6,721,117 issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	41	18
Additional paid-in capital	63,709	41,161
Accumulated deficit	(45,704)	(25,381)
Accumulated other comprehensive income	4	4
Total stockholders' equity	**18,050**	**15,802**
Total liabilities and stockholders' equity	**$ 21,078**	**$ 19,084**
Going concern and liquidity *[note 1]*		

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Loss and Comprehensive Loss

(In thousands, except per share and share amounts)

	Year Ended December 31,		
	2019	2018	2017
EXPENSES			
Research and development	$ 9,674	$ 5,868	$ 3,101
General and administrative	6,854	6,945	3,531
Total operating expenses	16,528	12,813	6,632
OTHER INCOME (EXPENSE)			
Interest income	170	171	21
Bargain purchase gain *[note 2]*	—	—	1,272
Contingent value rights recovery *[note 2]*	—	—	200
Gain on warrants	—	—	150
Loss on disposition of intangible asset *[note 5]*	—	—	(8,610)
Other expenses	(37)	(45)	(35)
Total other income	133	126	(7,002)
Net loss before income taxes	$ (16,395)	$ (12,687)	$ (13,634)
Recovery of deferred income taxes *[note 5]*	—	—	3,051
Net Loss	$ (16,395)	$ (12,687)	$ (10,583)
Comprehensive loss	$ (16,395)	$ (12,687)	$ (10,583)
Basic and diluted net loss per common share *[note 11 [g]]*	$ (1.99)	$ (3.61)	$ (22.07)
Shares used in computation of basic and diluted net loss per common share *[note 11 [g]]*	8,246,400	3,510,217	479,442

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total, Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2016	2,123	$ —	—	$ —	$ 2,667	$ 5	$ (2,062)	$ 610
Stock-based compensation expense	—	—	—	—	348	—	—	348
Settlement of stockholder loans with related parties	157	—	—	—	2,132	—	—	2,132
Shares issued on subscription	5	—	—	—	64	—	—	64
Shares held by OncoGenex Shareholders	273,671	3	—	—	—	—	—	3
Shares issued on conversion of Achieve common shares	821,012	8	—	—	13,040	—	—	13,048
Shares cancelled on conversion of Achieve common shares	(2,285)	—	—	—	—	—	—	—
Restricted Stock Unit Settlements	546	—	—	—	—	—	—	—
Restricted Stock Unit Settlements withheld and retired to treasury	(166)	—	—	—	—	—	(5)	(5)
Shares issues - Lincoln Park Capital	99,730	1	—	—	2,305	—	—	2,306
Purchase accounting adjustment	—	—	—	—	—	—	(44)	(44)
Net loss	—	—	—	—	—	—	(10,583)	(10,583)
Balance, December 31, 2017	1,194,793	12	—	—	20,556	5	(12,694)	7,879
Stock-based compensation expense	—	—	—	—	854	—	—	854
Restricted stock unit settlements	5,354	—	—	—	—	—	—	—
Adjustment of fractional shares on reverse stock split	(38)	—	—	—	—	—	—	—
Shares issued - from purchase agreement with Lincoln Park Capital	96,000	1	—	—	1,278	—	—	1,279
Shares issued - June 2018 public offering	1,160,500	1	9,158	—	12,193	—	—	12,194
Shares issued - October 2018 registered direct offering	1,789,258	2	—	—	4,958	—	—	4,960
Shares issued on exercise of warrants	330,500	—	—	—	1,324	—	—	1,324
Shares issued on conversion of Series A preferred shares	2,144,750	2	(8,579)	—	(2)	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(12,687)	(12,687)
Balance, December 31, 2018	6,721,117	18	579	—	41,161	4	(25,381)	15,802
Stock-based compensation expense	—	—	—	—	1,201	—	—	1,201
Restricted stock unit settlements	5,084	—	—	—	—	—	—	—
Adjustments to final October 2018 financing costs	—	—	—	—	4	—	—	4
Cumulative adjustment on adoption of lease standard	—	—	—	—	—	—	(3)	(3)

Shares issued - from purchase agreement with Lincoln Park Capital	374,000	—	—	—	792	—	—	792
Shares issued - December 2019 public offering	12,577,504	13	6,256	—	12,321	—	—	12,334
Adjustments to final June 2018 financing costs	—	—	—	—	116	—	—	116
Shares issued on exercise of warrants	1,107,813	1	—	—	4,198	—	—	4,199
Shares issued on conversion of Series A preferred shares	144,750	—	(579)	—	—	—	—	—
Shares issued on conversion of Series B preferred shares	8,554,910	9	(5,135)	—	(9)	—	—	—
Issuance of inducement warrants	—	—	—	—	3,925	—	(3,925)	—
Net loss	—	—	—	—	—	—	(16,395)	(16,395)
Balance, December 31, 2019	29,485,178	41	1,121	—	63,709	4	(45,704)	18,050

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Operating Activities:			
Net loss	$ (16,395)	$ (12,687)	$ (10,583)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on warrants *[note 7 and note 11[e]]*	—	—	(150)
Depreciation	31	60	59
Amortization	223	222	223
Stock-based compensation *[note 11[c]]*	1,201	854	348
Cumulative adjustment on adoption of lease standard	(3)	—	—
Deferred income tax (recovery) *[note 2 and 5]*	—	—	(3,051)
Bargain purchase gain *[note 2]*	—	—	(1,272)
Loss on disposition *[note 2]*	—	—	8,610
Contingent value rights recovery *[note 2]*	—	—	(200)
Changes in operating assets and liabilities:			
Amounts receivable	(1)	2	(9)
Prepaid expenses and other assets	195	(343)	(1,349)
Accounts payable	715	(69)	118
Accrued liabilities other	(328)	310	(2,185)
Accrued clinical liabilities	(812)	322	877
Accrued compensation	(52)	710	458
Other liabilities	—	—	—
Salaries payable	—	—	(1,028)
Lease obligation	10	(4)	27
Net cash used in operating activities	(15,216)	(10,623)	(9,107)
Financing Activities:			
Proceeds from share subscription	—	—	64
Proceeds from purchase agreement with Lincoln Park Capital, net of issuance costs	792	1,279	1,942
Proceeds from June 2018 public offering, net of issuance costs	—	12,194	—
Proceeds from exercise of warrants, net of issuance costs	4,199	1,324	—
Proceeds from October 2018 registered direct offering, net of issuance costs	—	4,960	—
Proceeds from December 2019 public offering, net of issuance costs	12,334	—	—
Taxes paid related to net share settlement of equity awards	—	—	(5)
Net cash provided by financing activities	17,325	19,757	2,001
Investing Activities:			
Cash received on reverse takeover of OncoGenex	—	—	12,648
Purchase of property and equipment	(53)	(46)	—
Proceeds on disposal of assets	—	10	—
Purchase of investments	(25)	(5,539)	—
Maturities of investments	5,114	450	—
Net cash provided by (used in) investing activities	5,036	(5,125)	12,648
Effect of exchange rate changes on cash	4	—	(1)
Net increase (decrease) in cash, cash equivalents and restricted cash	7,149	4,009	5,541
Cash, cash equivalents and restricted cash at beginning of year	9,565	5,556	15
Cash, cash equivalents and restricted cash at end of year	$ 16,714	$ 9,565	$ 5,556

See accompanying notes.

1. NATURE OF BUSINESS, BASIS OF PRESENTATION AND GOING CONCERN UNCERTAINTY

Achieve Life Sciences, Inc. (referred to as "Achieve," "we," "us," or "our") is a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation. We were incorporated in the state of Delaware, and operate out of Vancouver, British Columbia and Seattle, Washington.

On May 23, 2018, we effected a one-for-ten reverse stock split on our shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto have been retroactively adjusted for the stock split as if such stock split occurred on the first day of the first period presented. Certain amounts in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

On August 1, 2017, OncoGenex Pharmaceuticals, Inc., or OncoGenex, completed a transaction, or the Arrangement, with Achieve Life Science, Inc., or Achieve, as contemplated by the Merger Agreement between Achieve and OncoGenex dated January 5, 2017, or the Merger Agreement. Under the terms of the Merger Agreement, OncoGenex changed its name to Achieve Life Sciences, Inc., instituted an one-for-eleven reverse stock split, issued 821,011 shares of its common stock (after accounting for the elimination of resulting fractional shares) in exchange for all of the outstanding preferred shares, common shares and convertible debentures of Achieve, as a result Achieve became a wholly-owned subsidiary of OncoGenex, and is listed on the Nasdaq Capital Market under the ticker symbol ACHV.

These consolidated financial statements account for the Arrangement between OncoGenex and Achieve as a reverse merger, whereby Achieve is deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations of the Company for the year ended December 31, 2017 include the results of operations of only Achieve for the time period of January 1, 2017 through August 1, 2017 and include the results of the combined company following the completion of the Arrangement on August 1, 2017. This treatment and presentation is in accordance with ASC 805, "Business Combinations". Information relating to the number of shares, price per share and per share amounts of common stock are presented on a post- reverse stock split basis, as a reverse stock split in the ratio of one-for-eleven was effected in connection with the Arrangement.

Basis of Presentation

The consolidated financial statements include the accounts of Achieve and our wholly owned subsidiaries, Achieve Life Sciences Technologies Inc., Achieve Life Science, Inc., Extab Corporation, and Achieve Pharma UK Limited. All intercompany balances and transactions have been eliminated.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We have never been profitable and have incurred operating losses in each year since inception. Our net loss was $16.4 million, $12.7 million and $10.6 million for the years ending December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $45.7 million, cash, cash equivalents and short-term investments balance of $16.7 million and a positive working capital balance of $14.5 million. During the year ended December 31, 2019, net cash used in operations was $15.2 million Substantially all of our operating losses resulted from expenses incurred from general and administrative costs associated with our operations and research and development costs from our clinical development programs.

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. There is no assurance that we will obtain additional financing from other sources. We have, thus far, financed our operations through the closing of the Arrangement (Note 2—Reverse Merger) and equity financing (Note 11—Common Stock). 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.

Our current capital 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 candidates. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidate in clinical development.

The consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

2. REVERSE MERGER

The consolidated financial statements account for the Arrangement between us and OncoGenex, whereby OncoGenex acquired all of our outstanding preferred shares, common shares and convertible debentures, as a reverse merger wherein we are deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations include our results of operations for the twelve months ended December 31, 2017 and the results of OncoGenex following the completion of the Arrangement on August 1, 2017.

On August 1, 2017, our stockholders approved the Arrangement described above and on the same date, OncoGenex stockholders approved the Arrangement and a one-for-eleven reverse stock split of its common stock. The reverse stock split occurred immediately prior to the closing of the Arrangement. Resulting fractional shares were eliminated. All information in the financial statements and the notes thereto relating to the number of shares, price per share, and per share amounts of common stock are presented on a post-split basis.

Under the purchase method of accounting, OncoGenex's outstanding shares of common stock were valued using the closing price on NASDAQ of $46.20 as at August 1, 2017. There were 273,670 shares of common stock outstanding, as adjusted for the reverse stock split, on August 1, 2017, immediately prior to closing. The fair value of the OncoGenex outstanding stock options was determined using the Black-Scholes pricing model with the following assumptions: stock price of $46.20, volatility of 97.23% to 106.63%, risk-free interest rate of 1.31% to 1.54%, and expected lives ranging from 1.82 to 3.31 years. The fair value of the OncoGenex outstanding warrants was determined using the Black-Scholes pricing model with the following assumptions: stock price of $46.20, volatility of 90.33% to 106.08%, risk-free interest rate of 1.32% to 1.53%, and expected lives ranging from 1.91 to 3.24 years.

The final purchase price is summarized as follows (dollars in thousands, except per share amounts):

Shares of the combined company to be owned by OncoGenex equity holders		273,670
Multiplied by the price per share of OncoGenex stock	$	46.20
Value of shares of the combined company owned by OncoGenex equity holders	$	12,643
Fair value of options and warrants assumed	$	207
Fair value of contingent value rights assumed	$	200
Total purchase price	$	13,050

Under the purchase method of accounting, the total purchase price as shown in the table above is allocated to the OncoGenex net tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of the date of the completion of the Arrangement. The final purchase price allocation is as follows (in thousands):

Cash, cash equivalents and marketable securities	$	12,376
Prepaid expenses and other assets		518
Intangible assets license agreements		8,610
Accounts payable, accrued expenses and other liabilities		(4,054)
Deferred tax liability		(2,928)
Contingent value rights		(200)
Excess negative goodwill		(1,272)
Total purchase price		13,050

In accordance with ASC 805, “Business Combinations,” any excess of fair value of acquired net assets over purchase price (negative goodwill) has been recognized as a gain in the period the Arrangement was completed. We have reassessed whether all acquired assets and assumed liabilities have been identified and recognized and performed remeasurements to verify that the consideration paid, assets acquired, and liabilities assumed have been properly valued. The remaining excess has been recognized as a gain. There was no other impact to other comprehensive income.

OncoGenex issued contingent value rights, or each, a CVR and collectively, the CVRs, on July 31, 2017 to their existing stockholders as of July 27, 2017. One CVR was issued for each share of their common stock outstanding as of the record date for such issuance. Each CVR was a non-transferable right to potentially receive certain cash, equity or other consideration received by us in the event that we received any such consideration during the five-year period after consummation of the Arrangement as a result of the achievement of certain clinical milestones, regulatory milestones, sales-based milestones and/or up-front payment milestones relating to apatorsen, or the Milestones, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between us and an as of yet unidentified third party, as rights agent, or the CVR Agreement. The aggregate consideration to be distributed to the holders of the CVRs would have been equal to 80% of the consideration received by us as a result of the achievement of the Milestones less certain agreed to offsets, as determined pursuant to the CVR Agreement.

The contingent value rights expired on August 17, 2017, as we did not enter into any term sheets or agreement with third parties for the development or commercialization of apatorsen. A recovery of $0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss.

Pro Forma Results of Operations

The results of operations of OncoGenex are included in our consolidated financial statements following the date of the completion of the transaction on August 1, 2017. The following table presents pro forma results of operations and gives effect to the business combination transaction as if the transaction was consummated at the beginning of the period presented. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the retrospective periods or of the results that may occur in the future.

	For the Year Ended December 31,		
	2019	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	$ —	$ —	$ —
Net loss applicable to common shareholders	$ (16,395)	$ (12,687)	$ (20,111)
Net loss per share-basic and diluted	$ (1.99)	$ (3.61)	$ (41.95)
Weighted average shares	8,246,400	3,510,217	479,442

3. ACCOUNTING POLICIES

Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and notes thereto. Actual results could differ from these estimates. Estimates and assumptions principally relate to estimates of the fair value of our warrant liability, the initial fair value and forfeiture rates of stock options issued to employees and consultants, the estimated compensation cost on performance restricted stock unit awards, clinical trial and manufacturing accruals, estimated useful lives of property, plant, equipment and intangible assets, estimates and assumptions in contingent liabilities.

Cash Equivalents

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents, which we consider as available for sale and carry at fair value, with unrealized gains and losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of stockholders’ equity.

Short-Term Investments

Short-term investments consist of financial instruments purchased with an original maturity of greater than three months and less than one year. We consider our short-term investments as available-for-sale and carry them at fair value, with unrealized gains and losses, if any, reported as accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. Realized gains and losses on the sale of these securities are recognized in net income or loss. The cost of investments sold is based on the specific identification method.

Fair value of financial instruments

The fair value of our cash equivalents and marketable securities is based on quoted market prices and trade data for comparable securities. We determine the fair value of our warrant liability based on the Black-Scholes pricing model and using considerable judgment, including estimating stock price volatility and expected warrant life. Other financial instruments including amounts receivable, accounts payable, accrued liabilities other, accrued clinical liabilities and accrued compensation are carried at cost, which we believe approximates fair value because of the short-term maturities of these instruments.

Intellectual Property

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where we have not identified an alternative future use for the acquired rights, and are capitalized in situations where we have identified an alternative future use. No costs associated with acquiring intellectual property rights have been capitalized to date. Costs of maintaining intellectual property rights are expensed as incurred.

Intangible Assets

Our intangible assets are subject to amortization and are amortized using the straight-line method over their estimated period of benefit. We evaluate the carrying amount of intangible assets periodically by taking into account events or circumstances that may warrant revised estimates of useful lives or that indicate the asset may be impaired.

Goodwill

Goodwill acquired in a business combination is assigned to the reporting unit that is expected to benefit from the combination as of the acquisition date. Goodwill is tested for impairment on an annual basis or, more frequently, if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit.

Property and Equipment

Property and equipment assets are recorded at cost less accumulated depreciation. Depreciation expense on assets acquired under capital lease is recorded within depreciation expense. Depreciation is recorded on a straight-line basis over the following periods:

Computer equipment	3 years
Furniture and fixtures	5 years
Machinery and equipment	5 - 10 years
Leasehold improvements and equipment under capital lease	Over the term of the lease

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. We conduct our long-lived asset impairment analyses in accordance with ASC 360-10-15, "Impairment or Disposal of Long-Lived Assets." ASC 360-10-15 requires us to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the carrying values of assets and liabilities and their respective income tax bases and for operating losses and tax credit carry forwards. A valuation allowance is provided for the portion of deferred tax assets that is more likely than not to be unrealized. Deferred tax assets and liabilities are measured using the enacted tax rates and laws.

Research and Development Costs

Research and development costs are expensed as incurred, net of related refundable investment tax credits, with the exception of non-refundable advance payments for goods or services to be used in future research and development, which are capitalized in accordance with ASC 730, “Research and Development” and included within Prepaid Expenses or Other Assets depending on when the assets will be utilized.

Clinical trial expenses are a component of research and development costs. These expenses include fees paid to contract research organizations and investigators and other service providers, which conduct certain product development activities on our behalf. We use an accrual basis of accounting, based upon estimates of the amount of service completed. In the event payments differ from the amount of service completed, prepaid expense or accrued liabilities amounts are adjusted on the balance sheet. These expenses are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. We monitor each of these factors to the extent possible and adjust estimates accordingly.

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of the ASC 718, “Stock Compensation”, using the modified prospective method with respect to options granted to employees and directors. The expense is amortized on a straight-line basis over the graded vesting period.

Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four-year period. We also granted restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, we evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance provision or the occurrence of other events that may have caused the awards to accelerate and vest.

Segment Information

We follow the requirements of ASC 280, “Segment Reporting.” We have one operating segment, dedicated to the development and commercialization of cytisinicline for smoking cessation, with operations located in Canada and the United States.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on our available-for-sale marketable securities. We report the components of comprehensive loss in the statement of stockholders’ equity.

Loss per Common Share

Basic loss per common share is computed using the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed in accordance with the treasury stock method. The effect of potentially issuable common shares from outstanding stock options, restricted stock unit awards and warrants are anti-dilutive for all periods presented.

Warrants

We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company’s own stock, on the understanding that in compliance with applicable securities laws, the warrants require the issuance of registered securities upon exercise and therefore do not sufficiently preclude an implied right to net cash settlement. We classify warrants on the consolidated balance sheet as a liability which is revalued at each balance sheet date subsequent to the initial issuance. We also have warrants classified as equity and these are not reassessed for their fair value at the end

of each reporting period. Warrants classified as equity are initially measured at their fair value and recognized as part of stockholders' equity. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the warrants. Changes in the fair value of the warrants classified as liabilities are reflected in the consolidated statement of loss as gain (loss) on revaluation of warrants.

Reporting Currency and Foreign Currency Translation

Effective August 2, 2017, we changed the functional currency of our UK subsidiary from the Great British Pound to the U.S. dollar. As a result of the Arrangement, the UK subsidiary's primary economic environment has now changed from the UK to the United States. This has resulted in significant changes in economic facts and circumstances that clearly indicate that the functional currency has changed. We accounted for the change in functional currency prospectively.

The consolidated financial statements for the period of January 1, 2017 to August 2, 2017, are based on the UK subsidiary with a functional currency of GBP, and have been translated into the U.S. reporting currency using the current rate method as required by SFAS No. 52, "Foreign Currency Translation", ("SFAS 52") as follows: assets and liabilities using the rate of exchange prevailing at the balance sheet date; stockholders' deficiency using the applicable historic rate; and revenue and expenses using the monthly average rate of exchange. Translation adjustments have been included as part of the accumulated other comprehensive income

Our functional and reporting currency is the U.S. dollar. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates.

The functional currency of our foreign subsidiary is the U.S. dollar. For this foreign operation, assets and liabilities denominated in other than U.S. dollars are translated at the period-end rates for monetary assets and liabilities and historical rates for non-monetary assets and liabilities. Revenues and expenses denominated in other than U.S. dollars are translated at average monthly rates. Gains and losses from this translation are recognized in the consolidated statement of loss.

Recently Adopted Accounting Policies

In May 2014, the Financial Accounting Standards Board, or FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606): Revenue from Contracts with Customers, which guidance in this update will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance when it becomes effective. ASU No. 2014-09 affects any entity that enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principal of ASU No. 2014-09 is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which will be our fiscal year 2018 (or December 31, 2018), and entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Early adoption is permitted. We have updated our policies and procedures to reflect the adoption of ASU No. 2014-09. The adoption of this standard did not have an impact on our financial position or results of operations.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. For public business entities, the amendments in this Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018 The adoption of this standard did not have a significant impact on our financial position or results of operations.

In February 2016, the FASB established Topic 842, Leases, by issuing Accounting Standards Update ASU No. 2016-02, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. The new standard establishes a right-of-use, or ROU, model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than

12 months. Leases were classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of loss and comprehensive loss.

We adopted the standard on the effective date of January 1, 2019 and elected to use the modified retrospective method. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also elected the available practical expedients and implemented internal controls to enable the preparation of financial information on adoption.

The standard had a material impact on our consolidated balance sheets, but did not have an impact on our consolidated statements of loss and comprehensive loss. The most significant impact was the recognition of ROU assets, of $0.5 million, and lease liabilities, of $0.5 million, for operating leases, while our accounting for finance leases remained substantially unchanged.

In August 2018, the FASB issued Accounting Standards Update 2018-13, Fair Value Measurement, which both modifies and clarifies the disclosure requirements for fair value measurement. This update is effective for financial statements issued for fiscal years beginning after December 15, 2019, with early adoption permitted. The adoption of this standard did not have a significant impact on our financial position or results of operations.

4. FINANCIAL INSTRUMENTS AND RISK

For certain of our financial instruments, including cash and cash equivalents, amounts receivable, accounts payable, accrued liabilities other, accrued clinical liabilities and accrued compensation carrying values approximate fair value due to their short-term nature. Our cash equivalents and short-term investments are recorded at fair value.

Financial risk is the risk to our results of operations that arises from fluctuations in interest rates and foreign exchange rates and the degree of volatility of these rates as well as credit risk associated with the financial stability of the issuers of the financial instruments. Foreign exchange rate risk arises as a portion of our investments which finance operations and a portion of our expenses are denominated in other than U.S. dollars.

We invest our excess cash in accordance with investment guidelines, which limit our credit exposure to any one financial institution or corporation other than securities issued by the U.S. government. We only invest in A (or equivalent) rated securities with maturities of one year or less. These securities generally mature within one year or less and in some cases are not collateralized. At December 31, 2019 the average days to maturity of our portfolio of cash equivalents and marketable securities was zero days. We do not use derivative instruments to hedge against any of these financial risks.

5. INTANGIBLES

All of our intangible assets are subject to amortization and are amortized using the straight-line method over their estimated useful life.

We acquired license agreements, related to OncoGenex’s product candidate apatorsen, upon the acquisition of OncoGenex. As at the date of the acquisition, the agreements were determined to have a fair value of $8.6 million with an estimated useful life of 6 years. (Note 2—Reverse Merger)

In August 2017, we discontinued further development of apatorsen. We provided a notice of discontinuance to our former development partners for apatorsen, Ionis Pharmaceuticals, Inc., or Ionis, and a letter of termination to the University of British Columbia, or UBC, notifying them that we have discontinued development of apatorsen resulting in termination of all licensing agreements related to this product candidate. We believe that all financial obligations, other than continuing mutual indemnification obligations and our requirement to pay for out-of-pocket patent expenses incurred up to the date of termination and for abandoning the apatorsen patents and patent applications, under all apatorsen related agreements with Ionis and UBC, are no longer owed and no further payments are due. We recognized a loss on disposition of apatorsen of $8.6 million and a deferred income tax recovery of $2.9 million as a result of discontinuing the development program and providing a notice of discontinuance of the license agreements with Ionis.

We acquired license and supply agreements, in relation to cytisinicline, upon the acquisition of Extab Corporation, or Extab, in 2015. The agreements were determined to have a fair value of $3.1 million with an estimated useful life of 14 years.

The components of intangible assets were as follows:

	December 31, 2019			December 31, 2018		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (1,030)	$ 2,087	$ 3,117	$ (807)	$ 2,310

For the year ended December 31, 2019 and 2018 we recorded license agreement amortization expense of $0.2 million and $0.2 million, respectively. The following table outlines the estimated future amortization expense related to intangible assets held as of December 31, 2019:

Year Ending December 31,	
2020	223
2021	223
2022	223
2023	223
Thereafter	1,195
Total	**$ 2,087**

We evaluate the carrying amount of intangible assets periodically by taking into account events or circumstances that may warrant revised estimates of useful life or that indicate the asset may be impaired. We conducted an impairment analysis for long lived assets, including the license and supply agreements for the active pharmaceutical ingredient cytisinicline, and concluded no impairment has occurred as of December 31, 2019.

6. LICENSE AGREEMENTS

Sopharma License and Supply Agreements

In 2009 and 2010, we entered into a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma, AD, or Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries including Germany, France and Italy related to new oral dosage forms of cytisinicline providing enhanced stability. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, the trademark Tabex in all territories—other than certain countries in Central and Eastern Europe, Scandinavia, North Africa, the Middle East and Central Asia, as well as Vietnam, where Sopharma or its affiliates and agents already market Tabex—in connection with the marketing, distribution and sale of products. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-teens percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. We have agreed to cooperate with Sopharma in the defense against any actual or threatened infringement claims with respect to Tabex. Sopharma has the right to terminate the Sopharma License Agreement upon the termination or expiration of the Sopharma Supply Agreement. The Sopharma License Agreement will also terminate under customary termination provisions including bankruptcy or insolvency and material breach. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

A cross-license exists between us and Sopharma whereby we grant to Sopharma rights to any patents or patent applications or other intellectual property rights filed by us in Sopharma territories.

On May 14, 2015, we and Sopharma entered into an amendment to the Sopharma License Agreement. Among other things, the amendment to the Sopharma License Agreement reduced the royalty payments payable by us to Sopharma from a percentage in the mid-teens to a percentage in the mid-single digits and extended the term of the Sopharma License Agreement until May 26, 2029.

On July 28, 2017, we and Sopharma entered into the amended and restated Sopharma Supply Agreement. Pursuant to the amended and restated Sopharma Supply Agreement, for territories as detailed in the licensing agreement, we will exclusively purchase all of our cytisinicline from Sopharma, and Sopharma agrees to exclusively supply all such cytisinicline requested by us, and we extended the term to 2037. In addition, we will have full access to the cytisinicline supply chain and Sopharma will manufacture sufficient cytisinicline to meet a forecast for a specified demand of cytisinicline for the five years commencing shortly after the commencement of the agreement, with the forecast to be updated regularly thereafter. Each of us and Sopharma may terminate the Sopharma Supply Agreement in the event of the other party’s material breach or bankruptcy or insolvency.

University of Bristol License Agreement

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives for use in smoking cessation, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level. Any patents issued in connection with these applications would be scheduled to expire on February 5, 2036 at the earliest.

In consideration of rights granted by the University of Bristol, we agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize product candidates subject to the University of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement, we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we agreed to pay an initial amount of $37,500 upon the execution of the amended University of Bristol License Agreement, and additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the amended University of Bristol License Agreement, in addition to amounts under the original University of Bristol License Agreement of up to $3.2 million in the aggregate, tied to specific financing, development and commercialization milestones. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible, as provided in the original University of Bristol License Agreement, for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Up to December 31, 2019, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Unless otherwise terminated, the University of Bristol License Agreement will continue until the earlier of July 2036 or the expiration of the last patent claim subject to the University of Bristol License Agreement. We may terminate the University of Bristol License Agreement for convenience upon a specified number of days' prior notice to the University of Bristol. The University of Bristol License Agreement will terminate under customary termination provisions including bankruptcy or insolvency or its material breach of the agreement. Under the terms of the University of Bristol License Agreement, we had provided 100 grams of cytisinicline to the University of Bristol as an initial contribution.

Ionis and UBC License Agreements

In August 2017, we discontinued further development of apatorsen. We provided a notice of discontinuance to our former development partners for apatorsen, Ionis, and a letter of termination to UBC notifying them that we have discontinued development of apatorsen resulting in termination of all licensing agreements related to this product candidate. We believe that all financial obligations, other than continuing mutual indemnification obligations and our requirement to pay for out-of-pocket patent expenses incurred up to the date of termination and for abandoning the apatorsen patents and patent applications, under all apatorsen related agreements with Ionis and UBC, are no longer owed and no further payments are due.

7. FAIR VALUE MEASUREMENTS

Assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. For certain of our financial instruments including amounts receivable and accounts payable the carrying values approximate fair value due to their short-term nature.

ASC 820 "Fair Value Measurements and Disclosures," specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. In accordance with ASC 820, these inputs are summarized in the three broad level listed below:

- Level 1 – Quoted prices in active markets for identical securities.
- Level 2 – Other significant inputs that are observable through corroboration with market data (including quoted prices in active markets for similar securities).
- Level 3 – Significant unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability.

As quoted prices in active markets are not readily available for certain financial instruments, we obtain estimates for the fair value of financial instruments through third-party pricing service providers.

In determining the appropriate levels, we performed a detailed analysis of the assets and liabilities that are subject to ASC 820.

We invest our excess cash in accordance with investment guidelines that limit the credit exposure to any one financial institution other than securities issued by the U.S. Government. These securities are not collateralized and mature within one year.

A description of the valuation techniques applied to our financial instruments measured at fair value on a recurring basis follows.

Financial Instruments

Cash

Significant amounts of cash are held on deposit with large well-established U.S. and Canadian financial institutions.

U.S. Government and Agency Securities

U.S. Government Securities U.S. government securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. government securities are categorized in Level 1 of the fair value hierarchy.

U.S. Agency Securities U.S. agency securities are comprised of two main categories consisting of callable and non-callable agency issued debt securities. Non-callable agency issued debt securities are generally valued using quoted market prices. Callable agency issued debt securities are valued by benchmarking model-derived prices to quoted market prices and trade data for identical or comparable securities. Actively traded non-callable agency issued debt securities are categorized in Level 1 of the fair value hierarchy. Callable agency issued debt securities are categorized in Level 2 of the fair value hierarchy.

Corporate and Other Debt

Corporate Bonds and Commercial Paper The fair value of corporate bonds and commercial paper is estimated using recently executed transactions, market price quotations (where observable), bond spreads or credit default swap spreads adjusted for any basis difference between cash and derivative instruments. The spread data used are for the same maturity as the bond. If the spread data does not reference the issuer, then data that reference a comparable issuer are used. When observable price quotations are not available, fair value is determined based on cash flow models with yield curves, bond or single name credit default swap spreads and recovery rates based on collateral values as significant inputs. Corporate bonds and commercial paper are generally categorized in Level 2 of the fair value hierarchy; in instances where prices, spreads or any of the other aforementioned key inputs are unobservable, they are categorized in Level 3 of the hierarchy.

Warrants

We reassess the fair value of the common stock warrants classified as liabilities at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. Warrants that are classified as liabilities are categorized in Level 3 of the fair value hierarchy. A small change in the estimates used may have a relatively large change in the estimated valuation. Warrants that are classified as equity are not considered liabilities and therefore are not reassessed for their fair values at each reporting date. As of December 31, 2019, we had no warrants classified as liabilities.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

December 31, 2019	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 949	$ —	$ —	$ 949
Money market securities (cash equivalents)	15,715	—	—	15,715
Restricted cash (Note 13)	50	—	—	50
Total assets	**$ 16,714**	**$ —**	**$ —**	**$ 16,714**

December 31, 2018	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 1,070	$ —	$ —	$ 1,070
Money market securities (cash equivalents)	8,445	—	—	8,445
Restricted cash (Note 13)	50	—	—	50
Corporate bonds and commercial paper	—	5,089	—	5,089
Total assets	$ 9,565	$ 5,089	$ —	$ 14,654

Cash and cash equivalents and short-term investments (in thousands):

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 949	$ —	$ —	$ 949
Money market securities	15,715	—	—	15,715
Total cash and cash equivalents	$ 16,664	$ —	$ —	$ 16,664
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	$ 50	$ —	$ —	$ 50

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,070	$ —	$ —	$ 1,070
Money market securities	8,445	—	—	8,445
Total cash and cash equivalents	$ 9,515	$ —	$ —	$ 9,515
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	$ 50	$ —	$ —	$ 50
Corporate bonds and commercial paper	5,089	—	—	5,089
Total short-term investments	$ 5,089	$ —	$ —	$ 5,089

Our gross realized gains and losses on sales of available-for-sale securities were not material for the years ended December 31, 2019 and 2018.

All securities included in cash and cash equivalents have maturities of 90 days or less at the time of purchase. All securities included in short-term investments have maturities of within one year of the balance sheet date. The cost of securities sold is based on the specific identification method.

We only invest in A (or equivalent) rated securities with maturities of one year or less. We do not believe that there are any other than temporary impairments related to our investment in marketable securities at December 31, 2019, given the quality of the investment portfolio, its short-term nature, and subsequent proceeds collected on sale of securities that reached maturity.

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	Cost	Accumulated Depreciation	Net Book Value
December 31, 2019			
Computer equipment	$ 237	$ 213	$ 24
Furniture and fixtures	42	42	—
Leasehold improvements	36	16	20
Computer software	335	327	8
Equipment under capital lease	7	2	5
Total property and equipment	$ 657	$ 600	$ 57

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. We conduct our long-lived asset impairment analyses in accordance with ASC 360-10-15, "Impairment or Disposal of Long-Lived Assets." ASC 360-10-15 requires us to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

9. OTHER ASSETS

Other assets include deferred share issues costs, prepaid amounts related to insurance that will not be utilized in the next 12 months and deposits paid for office space in accordance with the terms of the operating lease agreements.

10. INCOME TAX

[a] On August 2, 2017, OncoGenex completed a reverse takeover with Achieve. OncoGenex changed its name to Achieve Life Sciences, Inc. We are a Delaware incorporated company subject to blended US Federal and state statutory rates for December 31, 2019, 2018 and 2017 of 21%, 21% and 34%, respectively. For the purposes of estimating the tax rate in effect at the time that deferred tax assets and liabilities are expected to reverse, management uses the furthest out available future tax rate in the applicable jurisdictions.
Income tax expense consisted of the following (in thousands):

(In thousands)	2019	2018	2017
Income taxes at statutory rates (at a rate of 21% for 2019 and 2018 and 34% for 2017)	$ (3,490)	$ (2,664)	$ (4,636)
Expenses not deducted for tax purposes	116	70	(174)
Effect of tax rate changes on deferred tax assets and liabilities	(13)	(1,416)	3,158
Rate differential on foreign earnings	(296)	(165)	314
Reduction in benefit of operating losses	—	—	—
Reduction in the benefit of other tax attributes	—	—	—
Investment tax credits	(84)	—	—
Change in valuation allowance	(3,246)	4,182	(1,683)
Book to tax return adjustments	(75)	20	—
Unrecognized tax benefits	7,192	—	—
Reversal of previously accrued taxes due to IRS reassessment	(221)		
Other	(104)	(27)	(14)
Income tax expense	$ (221)	—	$ (3,035)

[b] At December 31, 2019, we have investment tax credits of $2.9 million (2018—$2.6 million) available to reduce future Canadian income taxes otherwise payable. We also have non-capital loss carryforwards of $104.2 million (2018—$123.3 million) available to offset future taxable income in Canada, UK net operating loss carryforwards of $2.7 million (2018—$1.8 million) to offset future taxable income in the UK and federal net operating loss carryforwards of $25.3 million (2018—$17.6 million) to offset future taxable income in the United States.

The investment tax credits and non-capital losses and net operating losses for income tax purposes expire as follows (in thousands):

	Investment Tax Credits	US Net Operating Losses	Canadian Non-capital Losses	UK Net Operating Losses
2022	1	—	—	—
2023	—	—	—	—
2024	—	—	—	—
2025	244	—	—	—
2026	71	—	7,660	—
2027	—	—	6,082	—
2028	111	—	7,256	—
2029	317	9	1,712	—
2030	346	5	6,770	—
2031	486	17	12,354	36
2032	363	43	17,278	42
2033	193	2	23,240	54
2034	215	3	17,077	46
2035	122	654	3,112	27
2036	79	611	5,361	58
2037	22	8,763	(5,295)	493
2038	202	7,207	(3,179)	887
2039	201	7,977	4,785	1,048
	$ 2,973	$ 25,291	$ 104,213	$ 2,691

In addition, we have unclaimed tax deductions of approximately $15.5 million related to scientific research and experimental development expenditures available to carry forward indefinitely to reduce Canadian taxable income of future years. We also have research and development tax credits of $0.2 million available to reduce future taxes payable in the United States. The research and development tax credits expire in 2039.

[c] Significant components of our deferred tax assets as of December 31 are shown below (in thousands):

	2019	2018
Deferred tax assets		
Tax basis in excess of book value of assets	$ 891	$ 886
Non-capital loss carryforwards	33,166	37,332
Research and development deductions and credits	6,256	5,707
Stock options	315	171
§59(e) Capitalized R&D expenses	3,501	3,334
Accrued expenses	79	—
Other	181	170
Total deferred tax assets	44,389	47,600
Valuation allowance	(43,875)	(47,123)
Net deferred assets	514	477
Deferred tax liabilities		
Intangible assets	—	(474)
Right of use assets	(79)	—
Other	(435)	(3)
Total deferred tax liabilities	(514)	(477)
Net deferred tax assets	—	—

The potential income tax benefits relating to these deferred tax assets have not been recognized in the accounts as their realization did not meet the requirements of “more likely than not” under the liability method of tax allocation. Accordingly, a valuation allowance has been recorded and no net deferred tax assets have been recognized in all jurisdictions as at December 31, 2019.

[d] Under ASC 740, the benefit of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of the benefit of an uncertain tax position may be recognized if the position has less than a 50% likelihood of being sustained.

A reconciliation of the unrecognized tax benefits of uncertain tax positions for the year ended December 31, 2019 is as follows (in thousands):

	Year ended December 31,		
	2019	2018	2017
Balance at January 1	$ 717	$ 715	$ 715
Additions based on tax positions related to the current year	7	6	—
Deductions based on tax positions related to prior years	—	(4)	—
Balance at December 31	$ 724	$ 717	$ 715

As of December 31, 2019, unrecognized benefits of approximately $0.7 million, if recognized, would affect our effective tax rate, and would reduce our deferred tax assets.

Our accounting policy is to treat interest and penalties relating to unrecognized tax benefits as a component of income taxes. As of December 31, 2019 and December 31, 2018 we had no accrued interest and penalties related to income taxes.

We are subject to taxes in Canada, the UK and the U.S. until the applicable statute of limitations expires. Tax audits by their very nature are often complex and can require several years to complete.

Tax Jurisdiction	Years open to examination
Canada	2011 to 2019
United Kingdom	2012 to 2019
US	2016 to 2019

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to,

(1) reducing the U.S. federal corporate tax rate from 34 percent to 21 percent;
(2) eliminating the corporate alternative minimum tax;
(3) creating a new limitation on deductible interest expense; and
(4) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

As a result of when the Act was signed into law, our deferred tax assets and liabilities were required to be remeasured using the lower 21% federal rate as of December 31, 2017.

11. COMMON STOCK

[a] Authorized

150,000,000 authorized common voting shares, par value of $0.001, and 5,000,000 preferred shares, par value of $0.001.

[b] Issued and outstanding shares

Purchase Agreement and Financing with Lincoln Park Capital

On September 14, 2017 we and Lincoln Park Capital Fund, LLC, or LPC, entered into a share and unit purchase agreement, which was amended on March 12, 2020, or the Purchase Agreement, pursuant to which we have the right to sell to LPC up to $11.0 million in shares of our common stock, par value $0.001 per share, subject to certain limitations and conditions set forth in the Purchase Agreement. On May 22, 2018 we obtained the requisite stockholder authorization to sell shares of our common stock to LPC in excess of 20% of our outstanding shares of common stock (as of the date we entered into the Purchase Agreement) in order to be able to sell to LPC the full amount remaining under the Purchase Agreement.

Pursuant to the Purchase Agreement, LPC initially purchased 32,895 of our units, or the Units, at a purchase price of $30.40 per unit, with each Unit consisting of (a) one share of our common stock and (b) one warrant to purchase one-quarter of a share of common stock at an exercise price of $34.96 per share, or Warrant. Each Warrant became exercisable six months following the issuance date until the date that is five years and six months after the issuance date and is subject to customary adjustments. The Warrants were issued only as part of the Units in the initial purchase of $1.0 million and no warrants shall be issued in connection with any other purchases of common stock under the Purchase Agreement.

After the initial purchase, if our stock price is above $1.00, as often as every other business day over the 54-month term of the Purchase Agreement, and up to an aggregate amount of an additional $10.0 million (subject to certain limitations) of shares of common stock, we have the right, from time to time, in our sole discretion and subject to certain conditions to direct LPC to purchase up to 150,000 shares of common stock. The purchase price of shares of common stock pursuant to the Purchase Agreement will be based on prevailing market prices of common stock at the time of sales without any fixed discount, and we will control the timing and amount of any sales of common stock to LPC. As consideration for entering into the Purchase Agreement, we issued to LPC 12,352 shares of common stock in September 2017 and, in connection with the amendment of the Purchase Agreement in March 2020, we agreed to pay to LPC $0.1 million as an expense reimbursement. The consideration of 12,352 shares of our common stock were fair valued based on the closing price of our common stock as at the transaction date and recognized as part of offering expenses.

During the twelve months ended December 31, 2019, we offered and sold 374,000 shares of our common stock pursuant to the Purchase Agreement with LPC for gross proceeds of approximately $0.8 million. Since entering into the Purchase Agreement, from September 14, 2017 through December 31, 2019, we offered and sold an aggregate of 557,378 shares of our common stock, including the 32,895 shares that were part of the initial purchase of Units. These aggregate sales resulted in gross proceeds to us of approximately $4.4 million and offering expenses of $0.5 million.

June 2018 Public Offering

On June 19, 2018, we completed an underwritten registered public offering, pursuant to which we sold 710,500 Class A Units at a price per unit of $4.00 and 9,158 Class B Units at a price per unit of $1,000.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series A Convertible Preferred Stock, par value $0.001 per share, convertible at any time at the holder’s option into 250 shares of common stock and warrants to purchase 250 shares of common stock.

Each warrant was immediately exercisable, expires on the five-year anniversary of the date of issuance and is exercisable at a price per share of common stock of $4.00. Additionally, subject to certain exceptions, if, after the June 19, 2018, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the 2018 Measurement Period, which 2018 Measurement Period commences on June 19, 2018, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such 2018 Measurement Period exceeds $500,000 per trading day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then we may call for cancellation of all or any portion of the warrants then outstanding.

The Class A Units and Class B Units were not certificated and the shares of common stock, Series A Convertible Preferred Stock and warrants comprising such Units were immediately separable and were issued separately in the public offering. The Class A and B Units were offered by us pursuant to the registration statement on Form S-1 (File No. 333-224840), and each amendment thereto, which was initially filed with the SEC, on May 10, 2018 and declared effective by the SEC on June 14, 2018 and the registration statement on Form S-1 (File No. 333- 225649) filed by the us with the SEC pursuant to Rule 462(b) of the Securities Act of 1933 on June 14, 2018.

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or the Underwriter, on June 15, 2018, we granted the Underwriter a 45 day option, or the 2018 Overallotment Option, to purchase up to 450,000 additional shares of common stock and/or warrants to purchase up to 450,000 shares of Common Stock solely to cover over-allotments. The 2018 Overallotment Option was exercised in full on June 18, 2018.

The public offering raised total gross proceeds of $13.8 million and after deducting $1.6 million in underwriting discounts and commissions and offering expenses, we received net proceeds of $12.2 million

The underwriting discounts and commissions and offering expenses have been charged against the gross proceeds.

As of December 31, 2019, all 9,158 shares of the Series A Convertible Preferred Stock had been converted into 2,289,500 shares of common stock, and no shares of the Series A Convertible Preferred Stock remained outstanding.

October 2018 Registered Direct Offering

On October 3, 2018 we completed a registered direct offering, pursuant to which we sold 1,789,258 shares of common stock at a price per share of $3.1445. We also issued to the investors in a concurrent private placement unregistered warrants to purchase up to 0.5 shares of common stock for each share purchased in the registered direct offering with an exercise price of $3.1445 per share. The warrants were exercisable immediately upon issuance and will expire five years following the date of issuance.

The registered direct offering raised total gross proceeds of $5.6 million, and after deducting approximately $0.6 million in placement agent fees and offering expenses, we received net proceeds of $5.0 million.

The placement agent fees and offering expenses have been charged against the gross proceeds.

At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On June 7, 2019, we entered into an At The Market Offering Agreement, or the Offering Agreement, with H.C. Wainwright & Co., LLC, as agent, or H.C. Wainwright, pursuant to which we may offer and sell, from time to time and at our election, through H.C. Wainwright shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $6.0 million.

Pursuant to 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. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares of common stock from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

We are not obligated to make any sales of the shares of common stock under the Offering Agreement. The offering of shares of common stock pursuant to the Offering Agreement will terminate upon the earliest of (a) the sale of all of the shares of common stock subject to the Offering Agreement, (b) the termination of the Offering Agreement by H.C. Wainwright or us, as permitted therein, or (c) June 7, 2022.

We will pay H.C. Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of shares of common stock and have agreed to provide H.C. Wainwright with customary indemnification and contribution rights. We will also reimburse H.C. Wainwright for certain specified expenses in connection with entering into the Offering Agreement. The Offering Agreement contains customary representations and warranties and conditions to the placements of the shares of common stock pursuant thereto.

From June 7, 2019 to December 31, 2019 we did not offer any shares of our common stock for sale pursuant to the Offering Agreement. As of December 31, 2019, shares of our common stock having an aggregate value of approximately $6.0 million remained available for sale under the Offering Agreement.

The offering expenses and fees have been deferred and will be charged against gross proceeds.

December 2019 Public Offering

On December 17, 2019, we completed an underwritten registered public offering, pursuant to which we sold, 9,577,504 Class A Units at a price per unit of $0.60 and 6,256 Class B Units at a price per unit of $999.60.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series B Convertible Preferred Stock, par value $0.001 per share, convertible at any time at the holder’s option into 1,666 shares of common stock, and warrants to purchase 1,666 shares of common stock.

Each warrant was immediately exercisable, expires on the five year anniversary of the date of issuance and is exercisable at a price per share of common stock of $0.60, subject to adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect, provided, however, that the exercise price of the warrants cannot be reduced to an amount less than $0.06 per share of common stock. Additionally, subject to certain exceptions, if, after December 17, 2019, (i) the volume weighted average price of the common stock for each of 30 consecutive trading days, or the 2019 Measurement Period, which 2019 Measurement Period commences on the closing date, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such 2019 Measurement Period exceeds $500,000 per trading day and

(iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then the Company may call for cancellation of all or any portion of the warrants then outstanding.

The Class A Units and Class B Units were not certificated and the shares of common stock, Series B Convertible Preferred Stock and warrants comprising such Units were immediately separable and were issued separately in the public offering. The Class A and B Units were offered by us pursuant to the registration statement on Form S-1 (File No. 333-234530), and each amendment thereto, which was initially filed with the SEC on November 6, 2019 and declared effective by the SEC on December 17, 2019.

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or Ladenburg, on December 17, 2019, we granted Ladenburg a 45 day option, or the 2019 Overallotment Option, to purchase up to 3,000,000 additional shares of common stock and/or warrants to purchase up to 3,000,000 shares of common stock solely to cover over-allotments. The 2019 Overallotment Option was exercised in full on December 17, 2019.

The public offering raised total gross proceeds of $13.8 million and after deducting $1.5 million in underwriting discounts and commissions and offering expenses, we received net proceeds of $12.3 million.

The underwriting discounts and commissions and offering expenses have been charged against the gross proceeds.

As of December 31, 2019, 5,135 shares of the Series B Convertible Preferred Stock had been converted into 8,554,910 shares of common stock, and 1,121 shares of the Series B Convertible Preferred Stock remained outstanding.

Equity Award Issuances and Settlements

During the year ended December 31, 2019, we did not issue any shares of common stock to satisfy stock option exercises and issued 5,134 shares of common stock to satisfy restricted stock unit settlements, compared with the issuance of no shares of common to satisfy stock option exercises and 5,354 shares of common stock to satisfy restricted stock unit settlements for the year ended December 31, 2018.

[c] Stock options

2018 Equity Incentive Plan

As of December 31, 2019, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 1,336,055 common shares for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 732,000 were reserved for options currently outstanding and 604,055 were available for future equity grants.

Under the 2018 Plan, we may grant options to purchase common shares or restricted stock units to our employees, directors, officers and consultants. The exercise price of the options is determined by our board of directors but will be at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option is set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2018 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

2017 Equity Incentive Plan

As of December 31, 2019, we had reserved, pursuant to the 2017 Equity Incentive Plan, or the 2017 Plan, 272,660 common shares for issuance upon exercise of stock options, currently outstanding, by employees, directors and officers of ours. Upon the effectiveness of our 2018 Plan, we ceased granting equity awards under our 2017 Plan.

Under the 2017 Plan, we granted options to purchase common shares or restricted stock units to our employees, directors, officers and consultants. The exercise price of the options was determined by our board of directors but was at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option was set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2017 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

2010 Performance Incentive Plan

As of December 31, 2019, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 15,931 common shares for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 5,923 were reserved for options currently outstanding and 10,008 were reserved for restricted stock units currently outstanding.

Under the 2010 Plan we granted options to purchase common shares and restricted stock units to our employees, directors, officers and consultants. The exercise price of the options was determined by our board of directors and was at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option is set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2010 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

ASC 718 Compensation – Stock Compensation

We recognize expense related to the fair value of our stock-based compensation awards using the provisions of ASC 718. We use the Black-Scholes option pricing model as the most appropriate fair value method for our stock options and recognize compensation expense for stock options on a straight-line basis over the requisite service period. In valuing our stock options using the Black-Scholes option pricing model, we make assumptions about risk-free interest rates, dividend yields, volatility and weighted average expected lives, including estimated forfeiture rates of the options.

The expected life was calculated based on the simplified method as permitted by the SEC's Staff Accounting Bulletin 110, Share-Based Payment. We consider the use of the simplified method appropriate because of the lack of sufficient historical exercise data following the reverse merger of OncoGenex. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a U.S. Treasury instrument whose term is consistent with the expected life of the stock options. In addition to the assumptions above, as required under ASC 718, management made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest. Forfeiture rates are estimated using historical actual forfeiture rates. These rates are adjusted on a quarterly basis and any change in compensation expense is recognized in the period of the change. We have never paid or declared cash dividends on our common stock and do not expect to pay cash dividends in the foreseeable future.

The estimated fair value of stock options granted in the respective periods was determined using the Black-Scholes option pricing model using the following weighted average assumptions:

	2019	2018
Risk-free interest rates	2.52%	2.93%
Expected dividend yield	0%	0%
Expected life	5.97 years	5.68 years
Expected volatility	94.25%	88.23%

The weighted average fair value of stock options granted during the year ended December 31, 2019 was $1.33.

The results for the periods set forth below included stock-based compensation expense in the following expense categories of the consolidated statements of loss (in thousands):

	Year ended December 31,	
	2019	2018
Research and development	$ 364	$ 272
General and administrative	837	582
Total stock-based compensation	$ 1,201	$ 854

Options vest in accordance with terms as determined by our board of directors, typically over three or four years for employee and consultant grants and over one or three years for board of director option grants. The expiry date for each option is set by our board of directors with, which is typically seven to ten years. The exercise price of the options is determined by our board of directors but is at least equal to the fair value of the share at the grant date.

Stock option transactions and the number of stock options outstanding are summarized below:

	Number of Optioned Common Shares	Weighted Average Exercise Price
Balance, January 1, 2019	**665,585**	$ 15.65
Granted	345,350	1.73
Forfeited	(352)	2,450.80
Balance, December 31, 2019	**1,010,583**	**$ 10.05**

The following table summarizes information about stock options outstanding at December 31, 2019 regarding the number of ordinary shares issuable upon: (1) outstanding options and (2) vested options.

(1) Number of common shares issuable upon exercise of outstanding options:

Exercise Prices	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
$1.42 - $1.99	302,100	$ 1.42	9.08
$2.00 - $2.97	386,650	2.56	8.72
$2.98 - $3.37	167,750	3.37	8.57
$3.38 - $3.70	8,250	3	9
$3.71 - $16.46	35,000	4	9
$16.47 - $69.45	104,910	28.90	7.58
$69.46 - $206.25	2,190	186.98	5.57
$206.26- $1,286.45	853	465.93	4.47
$1,286.46 - $1,348.05	1,530	1,304.27	3.78
$1,348.06 - $1,960.20	1,350	1,605.51	1.62
	1,010,583	**$ 10.05**	**8.69**

(2) Number common shares issuable upon exercise of vested options:

Exercise Prices	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
$1.42 - $1.99	34,826	$ 1.42	9.08
$2.00 - $2.97	162,076	2.56	8.72
$2.98 - $3.37	59,410	3.37	8.57
$3.38 - $3.70	—	—	—
$3.71 - $16.46	—	—	—
$16.47 - $69.45	63,144	28.90	7.58
$69.46 - $206.25	2,190	186.98	5.57
$206.26- $1,286.45	853	465.93	4.47
$1,286.46 - $1,348.05	1,530	1,304.27	3.78
$1,348.06 - $1,960.20	1,350	1,605.51	1.62
	325,379	**$ 22.93**	**8.43**

As at December 31, 2019, and December 31, 2018, the total unrecognized compensation expense related to stock options granted was $1.8 million and $2.4 million, respectively, each of which is expected to be recognized into expense over a period of approximately 2.1 years.

The estimated grant date fair value of stock options vested during the years ended December 31, 2019, 2018 and 2017 was $0.9 million, $1.0 million and $0.6 million, respectively.

The aggregate intrinsic value of options exercised was calculated as the difference between the exercise price of the stock options and the fair value of the underlying common stock as of the date of exercise. The aggregate intrinsic value of options exercised for the years ended December 31, 2019, 2018 and 2017 was zero, zero and zero, respectively. At December 31, 2019, the aggregate intrinsic value of the outstanding options was zero and the aggregate intrinsic value of the exercisable options was zero.

[d] Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four-year period. We also grant restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers and key employees. At each reporting date, we are required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance provision. For the years ended December 31, 2019, 2018 and 2017, $0.4 million, $0.2 million and $0.1 million, respectively, of stock based compensation expense was recognized related to these awards.

The following table summarizes our restricted stock unit award activity during the year ended December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, January 1, 2019	**15,142**	**$ 30.53**
Released	(5,134)	33.54
Balance, December 31, 2019	**10,008**	**$ 28.99**

As of December 31, 2019, we had approximately $0.2 million in total unrecognized compensation expense related to our restricted stock unit awards which is to be recognized over a weighted-average period of approximately 1.58 years.

[e] Stock Warrants

On May 30, 2019, we entered into a Warrant Exercise Agreement, or the Exercise Agreement, with Armistice Capital Master Fund, Ltd., or Armistice. Pursuant to the Exercise Agreement, Armistice exercised (i) outstanding warrants to purchase 270,313 shares of our common stock with an exercise price of $3.1445 per share issued as part of the October 2018 financing and (ii) outstanding warrants to purchase 837,500 shares of our common stock with an exercise price of $4.00 per share issued as part of the June 2018 financing, for aggregate exercise proceeds to us of approximately $4.2 million, or, collectively, the Warrant Exercise.

As an inducement for the Warrant Exercise, we agreed to issue to Armistice a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of our common stock at an exercise price of $4.50 per share, or the New Warrant. We also agreed to file a registration statement covering the resale of the shares underlying the New Warrant Shares. The New Warrant and the shares underlying the New Warrant were offered to Armistice in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933.

Under ASC 260, the fair value of the New Warrant of $3.9 million was recognized into accumulated deficit on our consolidated balance sheet as at June 30, 2019. We determined the fair value of the New Warrant using the Black-Scholes pricing model with the following assumptions: stock price of $4.23, volatility of 97.16%, risk-free interest rate of 2.06% and expected term of six years.

The following is a summary of outstanding warrants to purchase common stock at December 31, 2019:

	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 financing	1,200,000	$ 4.5000	May 2025
(6) Warrants issued in December 2019 financing	23,000,000	$ 0.6000	Dec 2024

For the twelve months ended December 31, 2019, 837,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of $3.4 million and 270,313 of the warrants issued in the October 2018 financing were exercised at a per unit price of $3.1445, for proceeds of $0.8 million. For the twelve months ended December 31, 2018, 330,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of $1.3 million. No warrants were exercised for the year ended December 31, 2017. As at December 31, 2019, all of our outstanding warrants are classified as equity.

[f] 401(k) Plan

We maintain a 401(k) plan. Our securities are not offered as an investment option. Our shares are prohibited for inclusion our 401(k) plan, as well as any match of our shares to employee contributions.

[g] Loss per common share

The following table presents the computation of basic and diluted net loss attributable to common stockholders per share (in thousands, except per share and share amounts):

	Years ended December 31,		
	2019	208	2017
Numerator			
Net loss	$ (16,395)	$ (12,687)	$ (10,583)
Denominator			
Weighted average number of common shares outstanding	8,246,400	3,510,217	479,442
Basic and diluted net loss per common share	$ (1.99)	$ (3.61)	$ (22.07)

As of December 31, 2019, a total of 28.1 million options, restricted stock units and warrants, respectively, have not been included in the calculation of potential common shares as their effect on diluted per share amounts would have been anti-dilutive.

12. RELATED PARTY TRANSACTIONS

We entered into a consulting agreement with Ricanto, Ltd., or Ricanto, on September 17, 2015 to provide strategic consulting and advice concerning clinical development, regulatory matters and business planning. Richard Stewart and Anthony Clarke together own 100% of Ricanto. Richard Stewart is our Chief Executive Officer, or CEO, Chairman of the Board, and a principal stockholder. Anthony Clarke is our Chief Scientific Officer, President, a board director, and a principal stockholder. We incurred consulting fees from Ricanto of $0.1 million during the nine months ended September 30, 2016. The consulting agreement with Ricanto was terminated on August 1, 2017, immediately prior to the closing of the Arrangement. We did not incur any consulting fees from Ricanto in 2017. On July 18, 2017, Ricanto converted all amounts owed to it, totaling $0.6 million, into 475 shares of our common stock, prior to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into approximately 17,067 shares of common stock post-conversion. As of December 31, 2019, we had no outstanding amounts payable to Ricanto.

During 2016 we borrowed $0.2 million in total principal amount through two notes payable dated April 20, 2016 and December 8, 2016 from Richard Stewart. The notes mature and are payable upon demand one year from the date of issuance. Interest accrues at an annual rate of 3.5%. On July 24, 2017, Richard Stewart converted the $0.2 million, representing the entire amounts of principal and accrued interest owed, into 146 shares of our common stock, prior to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into approximately 5,246 shares of common stock post-conversion. As of December 31, 2019, we had no outstanding principal or accrued interest with the related party.

On March 7, 2017 we borrowed $20,000 through a note payable to a lender of ours. The note matures and is payable upon demand one year from the date of issuance. Interest accrues at an annual rate of 3.5%. On July 24, 2017, the lender converted the remaining amounts in principal and accrued interest, totaling $0.8 million, into 586 shares of our common stock, prior to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into approximately 182,743 shares of common stock post-conversion. As of December 31, 2019, we had no outstanding principal or accrued interest with the related party.

On July 19, 2017 we entered into a separation agreement with our former CEO. Pursuant to the separation agreement, for settlement of all salaries owed, we paid 238 shares of our common stock, prior to the closing of the Arrangement, representing 50% of the total amounts owed as accrued compensation and paid $0.4 million for the remaining 50%, subsequent to the closing of the Arrangement.

Pursuant to the terms of the Arrangement, each share was converted into approximately 8,551 shares of common stock post-conversion. As of December 31, 2019, we had no outstanding principal or accrued interest with the related party.

On July 20, 2017 we entered into a separation agreement with our former CFO. Pursuant to the separation agreement, for settlement of all salaries owed and as a separation payment, we paid 127 shares of our common stock, prior to the closing of the Arrangement, representing 50% of the total amounts owed as accrued compensation and paid $0.2 million for the remaining 50%, subsequent to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into approximately 4,563 shares of common stock post-conversion. As of December 31, 2019, we had no outstanding principal or accrued interest with the related party.
Michelle Griffin, the spouse of Scott Cormack, OncoGenex's former CEO and a current member of our board of directors, entered into a consulting agreement in 2013 with OncoGenex, which was amended thereafter. Immediately prior to the closing of the Arrangement, the consulting agreement was terminated. Pursuant to the consulting agreement, OncoGenex was obligated to pay to the consultant a termination fee of $0.6 million, which was accrued in OncoGenex's accrued liabilities immediately prior to the closing of the Arrangement. Subsequent to the closing of the Arrangement, we paid the full amount of the termination fees and no amounts were accrued on our balance sheet as at December 31, 2019.

13. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Seattle office operating lease	$ 173	$ 148	$ 25	$ —	$ —
Vancouver office operating lease - new	$ 204	$ 65	$ 133	$ 6	$ —
Total	$ 377	$ 213	$ 158	$ 6	$ —

Leases

We have operating leases for our corporate offices.

Operating leases with a term of 12 months or longer are included in ROU assets, other current liabilities, and operating lease liabilities on our consolidated balance sheets. Finance leases are included in property and equipment, other current liabilities, and other long-term liabilities on our consolidated balance sheets.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of our leases do not provide an implicit rate, we use the incremental borrowing rate of comparable companies from a representative peer group selected based on industry and market capitalization. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Lease Arrangements

We had an operating lease agreement for office space in Vancouver, Canada, which expired in January 2019. Pursuant to the operating lease agreement, we had the option to terminate the lease early without penalty at any time after January 1, 2017 so long as we provided three months prior written notice to the landlord. This lease was not renewed.

On November 19, 2018, we entered into a lease agreement for new office space in Vancouver, British Columbia, which commenced on February 1, 2019, and has a four-year term. Pursuant to this lease, we rent approximately 2,367 square feet of office space. The annual rent is approximately $0.1 million.

The future minimum annual lease payments under the Vancouver lease are as follows (in thousands):

2020	65
2021	66
2022	67
2023	6
Total	**$ 204**

In February 2015, we entered into an office lease with Grosvenor International (Atlantic Freeholds) Limited, or Landlord, pursuant to which we leased approximately 11,526 square feet located at 19820 North Creek Parkway, Bothell, Washington, 98011, commencing

on February 15, 2015. The initial term of this lease was set to expire on April 30, 2018, with an option to extend the term for one approximately three-year period. Our monthly base rent for the premises started at approximately $18,000 which commenced on May 1, 2015 and increased on an annual basis up to approximately $20,000. We received a construction allowance, for leasehold improvements that we made, of approximately $0.1 million. We were responsible for 17% of taxes levied upon the building during each calendar year of the term. We delivered to the Landlord a letter of credit in the amount of $0.2 million, in accordance with the terms of the lease, which the Landlord may draw upon for base rent or other damages in the event of our default under this lease. In August 2015 we exercised our expansion option for an additional 2,245 square feet of office space, which commenced on August 1, 2015. We did not exercise our renewal option under the lease agreement. We negotiated an early termination and the lease expired on March 31, 2018.

On December 11, 2017, we entered into a lease, or the New Lease, with 520 Pike Street, Inc., or Pike, pursuant to which we leased approximately 3,187 square feet located at Suite 2250 at 520 Pike Tower, Seattle, Washington, 98101, which commenced on March 1, 2018. The initial term of the New Lease will expire at the end of the month on the third anniversary of the New Lease.

Our monthly base rent for the premises started at approximately $11,685 which commenced on March 1, 2018 and will increase on an annual basis up to approximately $12,397. In addition, we paid a security deposit to Pike in the amount of $37,192, subject to periodic reductions in the amount of $12,397 after each of the first and second anniversaries of the New Lease, which Pike may retain for base rent or other damages, in the event of our default under the New Lease.

We may not assign or sublet all or any portion of the premises without the consent of Pike, and Pike shall be entitled to 50% of any profit which we may receive above and beyond the rental price of the New Lease. Upon receipt of notice of our intent to assign or sublease any portion of the leased premises, Pike may terminate that portion of the premises within 30 days, and provided, that if such portion constitutes 50% or more of the total square footage of the premises, Pike may terminate the New Lease in its entirety.

The future minimum annual lease payments under the New Lease are as follows (in thousands):

2020		148
2021		25
Total	**$**	**173**

Consolidated rent and operating expense relating to both the Vancouver, Canada and Seattle, Washington, and Bothell, Washington offices for years ended December 31, 2019, 2018 and 2017 was $0.2 million, $0.3 million and $0.6 million, respectively.

Other information related to leases was as follows:

	Year Ended December 31,	
	2019	**2018**
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 176	$ —
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 455	—
Weighted Average Remaining Lease Term		
Operating leases	2.16 years	—
Weighted Average Discount Rate		
Operating leases	9.97%	—

Guarantees and Indemnifications

We indemnify our officers, directors and certain consultants for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at its request in such capacity. The term of the indemnification period is equal to the officer’s or director’s lifetime.

The maximum amount of potential future indemnification is unlimited; however, we have obtained director and officer insurance that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations as of December 31, 2019.

We have certain agreements with certain organizations with which it does business that contain indemnification provisions pursuant to which it typically agrees to indemnify the party against certain types of third-party claims. We accrue for known indemnification issues when a loss is probable and can be reasonably estimated. There were no accruals for or expenses related to indemnification issues for any period presented.

Material Changes in Financial Condition

(in thousands)	December 31, 2019	2018
Total Assets	$ 21,078	$ 19,084
Total Liabilities	3,028	3,282
Total Equity	18,050	15,802

The increase in assets as at December 31, 2019 as compared to December 31, 2018 primarily relates to increase in cash and cash equivalents from the December 2019 public offering, warrant exercises and from our purchase agreement with LPC. The decrease in liabilities as at December 31, 2019 compared to December 31, 2018 was primarily due to lower clinical trial accruals associated with completion of our ORCA-1 trial in June 2019.

14. SEVERANCE CHARGES

As a requirement for the closing of the Arrangement, OncoGenex terminated the employment of one senior executive. Severance payable at the date of the transaction was $1.2 million and has been accounted for as part of the purchase price allocation (Note 5—Intangibles). The severance payable was settled following the completion of the Arrangement and no amounts were owing as at December 31, 2019.

15. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes the unaudited statements of operations for each quarter of 2019 and 2018 (in thousands, except per share amounts):

	March 31	June 30	September 30	December 31
2019				
Research and development	4,055	2,032	1,824	1,763
General and administrative	1,885	1,630	1,893	1,446
Total operating expenses	5,940	3,662	3,717	3,209
Other income	36	38	44	15
Net loss	(5,904)	(3,624)	(3,673)	(3,194)
Basic and diluted net loss per share	$ (0.88)	$ (0.50)	$ (0.45)	$ (0.30)
2018				
Research and development	1,201	1,045	1,541	2,081
General and administrative	1,813	1,751	1,753	1,628
Total operating expenses	3,014	2,796	3,294	3,709
Other income (expense)	(8)	8	54	72
Net loss	(3,022)	(2,788)	(3,240)	(3,637)
Basic and diluted net loss per share	$ (2.43)	$ (1.82)	$ (0.71)	$ (0.55)

16. SUBSEQUENT EVENTS

On March 12, 2020, we and LPC entered into Amendment No. 1 to the Purchase Agreement, or the Amendment, pursuant to which the term of the Purchase Agreement was extended from 30 months to 54 months and the number of shares of common stock that we may direct LPC to purchase from time to time pursuant to a Regular Purchase (as defined in the Purchase Agreement) was increased from 80,000 shares of common stock to 150,000 shares of common stock. Minimum closing stock price requirements were also removed for Regular Purchases and Accelerated Purchases (each as defined in the Purchase Agreement). In connection with the Amendment, we agreed to pay to LPC $0.1 million as an expense reimbursement.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures are also designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including the principal executive officer and the principal financial officer, of the effectiveness of the design and operation of the disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

We have not made any changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2019, management assessed the effectiveness of our internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013 Framework). Based on this evaluation, management has determined that our internal control over financial reporting was effective as of December 31, 2019.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION

On March 12, 2020, we and LPC entered into Amendment No. 1 to the Purchase Agreement, or the Amendment, pursuant to which the term of the Purchase Agreement was extended from 30 months to 54 months and the number of shares of common stock that we may direct LPC to purchase from time to time pursuant to a Regular Purchase (as defined in the Purchase Agreement) was increased from 80,000 shares of common stock to 150,000 shares of common stock. Minimum closing stock price requirements were also removed for Regular Purchases and Accelerated Purchases (each as defined in the Purchase Agreement). In connection with the Amendment, we agreed to pay to LPC $0.1 million as an expense reimbursement.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019, and is incorporated by reference into this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019, and is incorporated by reference into this Annual Report on Form 10-K by reference**.**

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2019:

	(a)		(b)		(c)	
Plan category	Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights		Weighted-average exercise price of outstanding options, warrants and rights		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	1,020,591	(1)	$ 10.05	(1)	604,055	(1)
Equity compensation plans not approved by security holders	—		—		—	
Total	1,020,591		$ 10.05		604,055	

(1) As of December 31, 2019, we maintained the following equity compensation plans, which were approved by security holders: (a) the 2000 Stock Incentive Plan, (b) the 2007 Performance Incentive Plan, (c) the 2010 Performance Incentive Plan, (d) the 2017 Equity Incentive Plan and (e) the 2018 Equity Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019, and is incorporated by reference into this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is set forth in our 2020 Proxy Statement to be filed with the SEC within 120 days of December 31, 2019, and is incorporated by reference into this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) Financial Statements

(2) All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	033-80623	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 the 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 the 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 B Convertible Preferred Stock, filed	8-K	033-80623	3.1	December 20, 2019	
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	
4.1	Specimen Certificate of Common Stock	10-Q	000-21243	4.1	November 10, 2008	
4.2	Form of Series A Warrant	8-K	033-80623	4.1	June 27, 2014	
4.3	Form of Series A-1 Warrant	8-K	033-80623	4.1	April 30, 2015	
4.4	Form of Pre-Funded Series B Warrant	8-K	033-80623	4.2	June 27, 2014	
4.5	Form of Series B Warrant	8-K	033-80623	4.3	June 27, 2014	
4.6	Form of Warrant (LPC)	8-K	033-80623	4.1	September 14, 2017	
4.7	Form of Common Stock Purchase Warrant (June 2018 Offering)	8-K	033-80623	4.1	June 20, 2018	
4.8	Form of Preferred Stock Certificate	8-K	033-80623	4.2	June 20, 2018	
4.9	Form of Common Stock Purchase Warrant (October 2018 Private Placement)	8-K	033-80623	4.1	October 1, 2018	
4.10	Form of Warrant (May 2019)	8-K	033-80623	4.1	June 3, 2019	
4.11	Form of Common Stock Purchase Warrant (December 2019 Offering)	8-K	033-80623	4.1	December 20, 2019	
4.12	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934					X
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	
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-Q	033-80623	10.7b	March 1, 2018	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.7c	Form of Achieve Life Sciences Restricted Stock Unit Agreement††	10-Q	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†† (p)	S-1	33-96112	10.19	September 25, 1995	
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	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	
10.24	Lease by and between 520 Pike Street, Inc. and Achieve Life Sciences, Inc., dated December 11, 2018	10-Q	033-80623	10.20	March 1, 2018	
10.25	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	
10.26	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	
10.27	Amendment No. 1 to Purchase Agreement, by and between Achieve Life Sciences, Inc. and Lincoln Park Capital Fund, LLC. dated as of September 14, 2017					X
10.28	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	
10.29	Warrant Exercise Agreement by and between Achieve Life Sciences, Inc. and Armistice Capital Master Fund, Ltd., dated May 30, 2019.	8-K	033-80623	10.1	June 3, 2019	
10.30	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					X
23.1	Consent of PricewaterhouseCoopers LLP					X
24.1	Power of Attorney (included on the signature page hereto)					X
31.1	Certification of Chief Executive pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**					X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

† 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.

†† Indicates management contract or compensatory plan or arrangement.

* The Company has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

** The certifications attached as Exhibits 32.1 and 32.2 accompany to this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHIEVE LIFE SCIENCES, INC.
(Registrant)

Date: March 13, 2020

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

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Cormack and John Bencich, jointly and severally, as such person's attorneys-in-fact, each with the power of substitution, for such person in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ RICHARD STEWART Richard Stewart	Chairman and Chief Executive Officer	Date: March 13, 2020
By: /s/ JOHN BENCICH John Bencich	Executive Vice President, Chief Financial Officer and Chief Operating Officer	Date: March 13, 2020
By: /s/ ANTHONY CLARKE Anthony Clarke	Director	Date: March 13, 2020
By: /s/ SCOTT CORMACK Scott Cormack	Director	Date: March 13, 2020
By: /s/ DONALD JOSEPH Donald Joseph	Director	Date: March 13, 2020
By: /s/ MARTIN MATTINGLY Martin Mattingly	Director	Date: March 13, 2020
By: /s/ H. STEWART PARKER H. Stewart Parker	Director	Date: March 13, 2020
By: /s/ JAY MOYES Jay Moyes	Director	Date: March 13, 2020

Exhibit 4.12

DESCRIPTION OF SECURITIES REGISTERED
UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Achieve Life Sciences, Inc. (the "Company," "we," or "our) had one class of capital stock registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

The following description of our common stock summarizes the material terms and provisions of the common stock. Because it is only a summary, it may not contain all the information that is important to you. For the complete terms of our common stock, please refer to our certificate of incorporation, as amended and restated, and our amended and restated bylaws, which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.12 is a part, and to the provisions of applicable Delaware law.

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.

Preferred Stock

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.

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 Delaware General Corporation Law, 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.

Exchange Listing

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

Transfer Agent and Registrar

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

Exhibit 10.27

AMENDMENT NO. 1 TO PURCHASE AGREEMENT

This Amendment No. 1 (the "Amendment") is entered into this 12th day of March, 2020 ("Amendment Effective Date"), by and between **ACHIEVE LIFE SCIENCES, INC.**, a Delaware corporation (the "Company"), and **LINCOLN PARK CAPITAL FUND, LLC**, an Illinois limited liability company (the "Investor"), and amends that certain Purchase Agreement, dated as of September 14, 2017, between the Investor and the Company (the "Purchase Agreement"). Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Purchase Agreement.

RECITALS

WHEREAS, Section 12(e) of the Purchase Agreement provides that the Purchase Agreement may be amended by a written instrument signed by both parties thereto.

WHEREAS, the Company and the Investor desire to amend the terms of the Purchase Agreement as set forth herein;

NOW THEREFORE, the parties hereto, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, hereby agree as follows:

1. Amendment and Restatement of Definition of "Base Prospectus" in the Purchase Agreement. Effective as of the Amendment Effective Date, Section 1(k) of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"(k) "Base Prospectus" means the Company's final base prospectus, dated February 11, 2019, a preliminary form of which is included in the Registration Statement, including the documents incorporated by reference therein."

2. Amendment and Restatement of Definition of "Maturity Date" in the Purchase Agreement. Effective as of the Amendment Effective Date, Section 1(v) of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"(v) Maturity Date" means the first day of the month immediately following the fifty-four (54) month anniversary of the Commencement Date."

3. Amendment and Restatement of Definition of "Registration Statement" in the Purchase Agreement. Effective as of the Amendment Effective Date, Section 1(dd) of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"(dd) "Registration Statement" means, collectively, (i) the effective registration statement on Form S-3 (Commission File No. 333-207670) filed by the Company with the SEC pursuant to the Securities Act for the registration of shares of its Common Stock,

including the Warrant Shares, and (ii) the effective registration statement on Form S-3 (Commission File No. 333-229019) filed by the Company with the SEC pursuant to the Securities Act for the registration of shares of its Common Stock, including the Purchase Shares and the Commitment Shares, as each such Registration Statement has been or may be amended and supplemented from time to time, including all documents filed as part thereof or incorporated by reference therein, and including all information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430B of the Securities Act, including any comparable successor registration statement filed by the Company with the SEC pursuant to the Securities Act for the registration of shares of its Common Stock, including the Purchase Shares, the Commitment Shares and the Warrant Shares."

4. **Amendment and Restatement of Second Sentence of Section 2(a) of the Purchase Agreement**. Effective as of the Amendment Effective Date, the second sentence of Section 2(a) of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"Beginning one (1) Business Day following the Commencement Date, the Company shall have the right, but not the obligation, in its sole and absolute discretion, to direct the Investor, by its delivery to the Investor of a Regular Purchase Notice from time to time, to purchase up to One Hundred and Fifty Thousand (150,000) Purchase Shares (each such purchase a "Regular Purchase"), at the Purchase Price on the Purchase Date (which share amount shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction that occurs on or after the date of this Agreement); and provided, further, that the Investor's committed obligation under any single Regular Purchase shall not exceed One Million Dollars ($1,000,000), unless the parties mutually agree to increase the dollar amount of any Regular Purchase on any Purchase Date at the applicable Purchase Price."

5. **Deletion of Second Sentence of Section 2(b) of the Purchase Agreement**. Effective as of the Amendment Effective Date, the second sentence of Section 2(b) of the Purchase Agreement is hereby deleted in its entirety.

6. **Deletion of Section 2(d) of the Purchase Agreement**. Effective as of the Amendment Effective Date, Section 2(d) of the Purchase Agreement is hereby deleted in its entirety.

7. **Amendment and Restatement of Last Paragraph of Section 10 of the Purchase Agreement**. Effective as of the Amendment Effective Date, the last paragraph of Section 10 of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"In addition to any other rights and remedies under applicable law and this Agreement, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, the Company shall not deliver to the Investor any Regular Purchase Notice or Accelerated Purchase Notice, and the Investor shall not purchase any shares of Common Stock under this Agreement."

6. **Expense Reimbursement**. In consideration for the Investor's execution and delivery of this Amendment, the Company shall cause to be paid to the Investor, on or prior to the close of business on March 19, 2020, $120,000 (the "Expense Reimbursement") by wire transfer of immediately available funds to an account designated by the Investor by written notice to the Company on or prior to the date of this Amendment, for reimbursement of the reasonable expenses incurred by the Investor in connection with its commitment hereunder (including, without limitation, the reasonable legal fees and disbursements incurred by the Investor). For the avoidance of doubt, the full amount of the Expense Reimbursement shall be due and payable to the Investor as of the date of this Amendment, whether or not the any additional Purchase Shares are purchased by the Investor under the Agreement, as amended by this Amendment, from and after the Amendment Effective Date and irrespective of any termination of the Agreement, as amended by this Amendment.

7. **No other amendment**. Except as expressly set forth above, all other terms and conditions of the Purchase Agreement shall remain in full force and effect, without amendment thereto.

8. **Representations and Warranties.** Each party hereto represents and warrants as of the date hereof that such party has full power and authority to enter into the Amendment, and that when executed and delivered by such party, and assuming execution and delivery by the other parties, will constitute a legal, valid and binding obligation of such party, enforceable against it in accordance with its terms, except to the extent that such enforcement may be subject to applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application relating to or affecting enforcement of creditors' rights and laws concerning equitable remedies.

9. **Entire Agreement.** The Purchase Agreement (including the Exhibits and Schedules thereto), as amended by this Amendment, constitutes (along with the documents referred to in the Purchase Agreement) a complete and exclusive statement of the terms of the agreement between the Company and the Investor with respect to its subject matter, and any reference to the Purchase Agreement (including the Exhibits and Schedules thereto) shall be a reference to the Purchase Agreement (including the Exhibits and Schedules thereto) as amended hereby.

10. **Governing law**. This Amendment shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois.

11. **Counterparts**. This Amendment may be executed in counterparts, all of which taken together shall constitute one and the same original and binding instrument and shall become effective when all counterparts have been signed by each party and delivered to the other parties hereto, it being understood that all parties hereto need not sign the same counterpart.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their respective authorized officer as of the Amendment Effective Date.

THE COMPANY:

ACHIEVE LIFE SCIENCES, INC.

By: /s/ John Bencich
Name: John Bencich
Title:

INVESTOR:

LINCOLN PARK CAPITAL FUND, LLC
BY: LINCOLN PARK CAPITAL, LLC
BY: ALEX NOAH INVESTORS, INC.

By: /s/ Jonathan Cope
Name: Jonathan Cope
Title: President

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Achieve Life Sciences Technologies Inc., incorporated under the federal laws of Canada

Achieve Life Science Inc., a Delaware Corporation

Extab Corporation, a Delaware Corporation

Achieve Pharma UK Limited, a Limited Company in the United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File Nos. 333-56704, 333-135697, 333-144552, 333-153206, 333-168820, 333-190480, 333-197937, 333-206569, 333-221473, 333-228253 and 333-236059), Form S-1 (File Nos. 333-232817 and 333-228596) and Form S-3 (File Nos. 333-184829, 333-207670 and 333-229019) of Achieve Life Sciences, Inc. of our report dated March 13, 2020 relating to the consolidated financial statements, which appears in this Form 10-K.

Vancouver, Canada,

March 13, 2020

/s/ PricewaterhouseCoopers LLP

Chartered Professional Accountants

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, Richard Stewart, certify that:

1. I have reviewed this annual report on Form 10-K of Achieve Life Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ RICHARD STEWART
Richard Stewart
Chairman and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, John Bencich, certify that:

1. I have reviewed this annual report on Form 10-K of Achieve Life Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2020

/s/ JOHN BENCICH

John Bencich
Executive Vice President, Chief Financial Officer and Chief Operating Officer

Exhibit 32.1

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Richard Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 13, 2020

/s/ RICHARD STEWART

Richard Stewart
Chairman and Chief Executive Officer

Exhibit 32.2

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, John Bencich, Executive Vice President, Chief Financial Officer and Chief Operating Officer of Achieve Life Sciences, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 13, 2020

/s/ JOHN BENCICH
John Bencich
Executive Vice President, Chief Financial Officer and Chief Operating Officer