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, 2018
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	**Name of Exchange on Which Registered**
Common Stock, par value $0.001 per share	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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, 2018, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was $15,058,692, computed with reference to the price at which the Common Stock was last sold on June 30, 2018. As of March 14, 2019, 6,721,200 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement for its 2019 Annual Meeting of Stockholders ("Proxy Statement"), to be filed within 120 days of the Registrant's fiscal year ended December 31, 2018, 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. The United States Adopted Names, or USAN, Council adopted cytisinicline as the non-proprietary, or generic, name for the substance also known as cytisine during the third quarter of 2018. Our focus is to address the global smoking health epidemic, which is a leading cause of preventable death and is responsible for approximately seven million deaths annually worldwide.

Cytisinicline is an established 25-day 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 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 smoking through antagonistic properties. The currently-marketed 1.5 mg cytisinicline dosing schedule reflects that of an anti-addiction medication, with downward dose titration over a period of 25 days.

Investigational New Drug, or IND-enabling, non-clinical toxicology studies completed to date have been sponsored by the National Center for Complementary and Integrative Health, or NCCIH, division of the National Institutes of Health, or NIH, in addition to the National Cancer Institute. In June 2017, we filed our IND application for cytisinicline with the U.S. Food and Drug Administration, or FDA, which included NCCIH sponsored non-clinical studies.

In August 2017, we initiated a 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 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. Of the 36 subjects, 24 were to be 18-65 years and 12 were to be greater than 65 years of age. Preliminary results on the 24 smokers (18-65 years) were announced in February 2018 and final results were presented at the annual Society for Research on Nicotine and Tobacco, or SRNT, meeting in February 2019. The study randomized a total of 26 subjects. This included only 2 of the intended 12 subjects greater than age 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 achieving 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 observed were mostly mild with transient headaches as the most commonly reported event. No severe or serious adverse events 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 whether additional drug-to-drug interactions studies will be required prior to any future New Drug Application, or 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 human 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.

A new cytisinicline tablet with improved shelf life has been formulated and recently launched commercially by Sopharma 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 of this new formulation of cytisinicline was well tolerated.

In October 2018, we initiated the ORCA-1 trial, a Phase 2b optimization study in approximately 250 smokers in the United States, or U.S. 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 and potentially other indications. This Phase 2b trial will evaluate both the 1.5 mg and 3.0 mg doses of cytisinicline on a declining titration schedule as well as three times daily dosing, both over 25 days. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. All subjects are treated for 25 days and followed up for a further four weeks. The primary efficacy endpoint is reduction in the number of cigarettes consumed during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 is being conducted at eight centers across the U.S. In February 2019, we announced that the trial had completed enrollment with 254 smokers and top line results are expected in mid-2019.

In December 2018, we announced that 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 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 trial to assess the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. This study will be performed in smokers who will receive one single dose of cytisinicline. The dosage of cytisinicline will be increased in separate groups of subjects per dose level until stopping criteria (based on the occurrence of dose-limiting adverse events) are reached. This study is a requirement for our future application for marketing approval of cytisinicline.

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.

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.

The 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. The consolidated results of

operations for the year ended December 31, 2016 include only the consolidated results of operations of Achieve and do not include historical results of OncoGenex. 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 alkyloid from the seeds of the *Laburnum anagyroides* plant. Cytisinicline is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and the reward and satisfaction associated with smoking.

Cytisinicline is an established 25-day smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by our partner Sopharma 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. Tabex™ is currently marketed in a number of countries in Central and Eastern Europe, as well as in other geographic regions, as an Over-the-Counter drug, or OTC.

Cytisinicline Mechanism of Action

Cytisinicline is a partial agonist that binds with high affinity to the alpha-4 beta-2, or a4b2, 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 a4b2 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 dependence. Cytisinicline is believed to act as a partial agonist at the a4b2 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 U.S. and intend 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 dependence to address the limitations of both prescription drugs and OTC products. We believe that a substantial market exists in the U.S., 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 U.S. and subsequently to other countries outside of Sopharma’s territory.

IND-enabling, non-clinical toxicology studies completed to date have been sponsored by the NCCIH, division of the NIH, in addition to the National Cancer Institute. In June 2017, we filed our IND application for cytisinicline with the FDA which included NCCIH sponsored non-clinical studies.

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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 achieving 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 observed were mostly mild with transient headaches as the most commonly reported event. No severe or serious adverse events were observed in the study.

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Cytisinicline Clinical Trials

Cytisinicline has been previously tested in two large, randomized 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 independent groups was to evaluate the efficacy and safety of cytisinicline according to current clinical development standards.

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 adverse events (upper abdominal pain, nausea, dyspepsia and dry mouth; cytisinicline 51/370 (13.8%) and placebo 30/370 (8.1%). The safety profile of cytisinicline was similar to that of a placebo with no other significant differences in the rate of side effects in the two trial arms.

A summary of adverse events 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 cytisinicline and five with placebo), cardiac (four with cytisinicline and two with placebo), musculoskeletal and connective tissue (three with cytisinicline 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 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 adverse events were slightly higher in the cytisinicline arm compared with the NRT arm. The most frequent adverse events for cytisinicline were nausea and vomiting (30/665 (4.6%)) and sleep disorders

(28/665 (4.2%)). Reports of these same adverse events in the NRT arm were as follows: nausea and vomiting (2/655 (0.3%)) and sleep disorders (2/655 (0.3%)).

A summary of adverse events 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.

Safety Reporting

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

OVERVIEW OF MARKET AND TREATMENT

Overview of the Tobacco Epidemic

The U.S. National Institutes of Health, or NIH, and the World Health Organization, or WHO, estimate that approximately 1.1 billion people globally are smokers and that 7 million people die annually from diseases related to tobacco use including 890,000 from passive smoke. This figure is projected to grow to 8 million by 2030. The U.S. Centers for Disease Control, or CDC, estimate that in 2017 approximately 14% of all U.S. adults (34.3 million people) were cigarette smokers.

Cigarette smoking is responsible for more than 480,000 deaths per year in the U.S., including more than 41,000 deaths resulting from secondhand smoke exposure. This is 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. Smoking remains the single largest preventable cause of death worldwide and in the U.S.

CDC estimates that the annual cost of smoking related illnesses in the U.S. is more than $300 billion annually in direct medical care and lost productivity. Over 16 million people in the U.S. are living with a disease caused by smoking. Smoking causes 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 or alcohol. The CDC estimates that more people are addicted to nicotine than any other drug and report that nearly 70% of smokers desire to quit and 55% make a quit attempt each year. Despite the high number of attempts, only about 7% of people are successful in their quit attempt each year. Additionally, up to 60% of people who quit smoking relapse in the first year due to the addictive nature of nicotine.

One increasingly popular method as an 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 growing population of people who are addicted to nicotine.

The FDA considers e-cigarette use as an epidemic, particularly in youth. From 2017 to 2018, vaping increased 78 percent among high school students (11.7% to 20.8%) and 48 percent among middle school students (3.3% to 4.9%).

The Global Smoking Cessation Market

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

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

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

The vast majority of Over-the-Counter, or OTC, smoking cessation aids are NRTs. NRTs come in many forms, including gums, lozenges and patches, and although they are marketed at a lower price point, they 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, Achieve 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, 2018, we have 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 U.S., 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 U.S. 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 U.S., 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 U.S., Medicaid currently covers all smoking cessation products including Chantix and Zyban. In March 2010, the Patient Protection and Affordable Care Act, 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 Patient Protection and Affordable Care Act, or 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 U.S. 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. is currently a member state of the EU. However, the U.K. has signaled its intention to withdraw from the EU, which is commonly known as BREXIT. Following BREXIT, if it occurs, the U.K. would no longer be a member state within the EU. 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. Further, the EMA is currently located in the U.K. but is relocating to The Netherlands. It is possible that BREXIT will result in disruption to the EMA's review process.

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 U.S. 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 225 acres of *Laburnum* trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria and is in the process of planting another 150 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 U.S. 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 U.S. 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 U.S. and in major market countries that we consider important to the development of our business worldwide. As of December 31, 2018, we had a portfolio of two international PCT applications and one national phase of patent applications in Australia, Canada, China, Europe, Japan, S. Korea, Mexico, New Zealand, South Africa, the U.K. and the U.S. This portfolio includes composition of matter and methods of use for novel cytisinicline derivatives.

We intend to take one of the above-noted PCT applications into national phase in 2019. 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, Pharmacia Polanica, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, zpharm, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm, Adamed, Aflofarm 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 U.S. – 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 and could be more cost-effective to patients. 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 U.S. 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, 2018, we had a total of 13 employees, of whom five 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, our company, then named OncoGenex Pharmaceuticals, Inc., completed its merger, or the Arrangement, with Achieve, as contemplated by the Merger Agreement between the companies. We then changed our name to Achieve Life Sciences, Inc. As a result of the Arrangement, Achieve became our wholly owned subsidiary. 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 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

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.

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

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

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

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

- our commercialization activities and arrangements;
- the progress and results of our research and development programs;
- the progress of our non-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals for our product candidate;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights with respect to our intellectual property;
- the effect of competing technological and market developments;
- the effect of changes and developments in our existing collaborative, licensing and other relationships; and
- the terms of any new collaborative, licensing 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 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, 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. For example, our management team consists of certain executive officers of Achieve prior to the merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. In addition, it may be more 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 in our post-merger company 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 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 newly 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 newly enacted federal tax law.

Risks Related to the Development of Our Product Candidate Cytisinicline

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

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

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

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

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

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

- delays in reaching agreement on acceptable terms with clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays in recruiting qualified patients in its clinical trials;
- failure by clinical sites, CROs or other third parties to adhere to clinical trial requirements;
- failure by clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;

- patients terminating enrollment in our clinical trials;
- adverse events or tolerability issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;
- inability to generate satisfactory non-clinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- animal toxicology issues significant enough for the FDA or other regulatory agencies to disallow investigation in humans;
- occurrence of adverse events associated with our product candidate;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of cytisinicline;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in ongoing or other planned indications for cytisinicline; and
- delays in the manufacture 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;
- 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 225 acres of *Laburnum* trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria and is in the process of planting another 150 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. Although Sopharma has plans to plant significant numbers of additional trees, there is no guarantee that they will do so or that the trees will produce the anticipated yield of cytisinicline. In the event we are no longer able to obtain cytisinicline from Sopharma, or in sufficient quantities, we may not be able to produce our proposed products and our business will be adversely affected.

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

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

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

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

If we decide to conduct clinical trials in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. Failure to meet such regulatory requirements could delay our clinical trials, the approval, if any, of cytisinicline by the FDA or other regulatory authorities, or the commercialization of cytisinicline, or result in higher costs or deprive us of potential product revenues.

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

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

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

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

or more shutdowns, we cannot predict the ongoing impact of such shutdowns on our business, or the degree to which funding would be restored to the FDA or other agencies having an impact on our business.

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

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

We will need approval from the FDA, to commercialize cytisinicline in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize cytisinicline in those jurisdictions. In order to obtain FDA approval of cytisinicline, we must submit an NDA to the FDA, demonstrating that cytisinicline is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of cytisinicline or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in data that the FDA considers safe and effective for the proposed indications of cytisinicline. The FDA has substantial discretion in the product approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory approval for cytisinicline. Failure to obtain approval from the FDA or comparable regulatory authorities in foreign jurisdictions to commercialize cytisinicline will leave us without saleable products and therefore without any source of revenues. In addition, the FDA may require us to conduct additional clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product or permit continued marketing, if previously approved. If conditional marketing approval is obtained, the results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. In foreign jurisdictions, the regulatory approval processes generally include the same or similar risks as those associated with the FDA approval procedures described above. We cannot be certain that we will receive the approvals necessary to commercialize cytisinicline for sale either within or outside the United States.

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

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

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

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

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

could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or the Healthcare Reform Law, requires manufacturers of products, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and

ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

On January 20, 2017, President Donald Trump issued an Executive Order to initiate the repeal of the Healthcare Reform Law and we 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 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 prescription drugs for smoking cessation, but not over-the-counter treatments. If these provisions are repealed, in whole or in part, our business, financial condition, or results of operations could be negatively affected.

The United Kingdom is currently a member state of the European Union. However, the United Kingdom has signaled its intention to withdraw from the European Union (commonly known as Brexit). If Brexit, which is likely to occur in 2019, does occur, the United Kingdom will no longer be a member state within the European Union. Since a significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union, Brexit could materially change the regulatory framework applicable to the approval of cytisinicline, which could have a material adverse effect on us and our operations. Brexit may also result in other significant regulatory and legislative changes in the United Kingdom, which could, for example, affect the pricing of pharmaceutical products in the United Kingdom, which could in turn result in diminished performance for us. Even if the substance of regulatory changes resulting from Brexit does not have a significant impact on our operations, it is reasonable to expect that we would incur potentially significant costs in connection with complying with any new regulations. Further, the European Medicines Agency is currently located in the United Kingdom. It is possible that Brexit would result in the relocation of the European Medicines Agency or disruption to the European Medicines Agency's review process, either of which could have an adverse effect on our operations in the United Kingdom and the European Union.

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

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

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

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

Risks Related to our Business Operations

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

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

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

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. We expect to need additional scientific, technical, operational, financial and other personnel. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Richard Stewart, John Bencich, Cindy Jacobs, Anthony Clarke and Jaime Xinos. In addition, although we have entered into employment agreements with each of Mr. Stewart, Mr. Bencich, Dr. Jacobs, Dr. Clarke and Ms. Xinos, such agreements permit those executives to terminate their employment with us at any time, subject to providing us with advance written notice.

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

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

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

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, Pharmacia Polanica, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, zpharm, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm, Adamed, Aflofarm 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; and
- 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 a herbal or homeopathic product. Other than regulatory exclusivity or other limitations, there may be little to nothing to stop these third parties from manufacturing, selling or distributing cytisinicline. Because we have no ability to set rigorous safety standards or control processes over third party manufacturers, sellers or distributors of cytisinicline, excluding Sopharma, these formulations of cytisinicline may be unsafe or cause adverse effects to patients and negatively impact the reputation of cytisinicline as a safe and effective smoking cessation aid.

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

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

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

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

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

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

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

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

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

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

Risks Related to our Intellectual Property

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

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

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

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

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

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

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

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

It is also possible that we have failed to identify relevant third-party patents or applications. 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; and
- period-to-period fluctuations in our financial results.

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

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, including in circumstances where such declines occur in close proximity to the announcement of clinical trial results. Additionally, our stock price and those of other biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

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

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

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

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

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

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 may seek to raise additional financing 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 15, 2019, there were approximately 17 stockholders of record and there were approximately 6,013 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, 2018 were made by us or on our behalf.

In October 2018, we sold unregistered warrants to purchase 894,626 shares of common stock, which is more fully described in our Current Report on Form 8-K filed with the SEC on October 1, 2018.

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, 2018, 2017 and 2016 and consolidated balance sheet data as of December 31, 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. The selected statements balance sheet data as of
December 31, 2016 set forth below have been derived from the audited consolidated financial statements for such years not included 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 of operations and balance sheet data shown for the year ended December 31, 2016 reflect only those of Achieve prior to the Arrangement, and do not reflect the results of OncoGenex. The historical results presented are not necessarily indicative of future results.

	December 31,		
	2018	2017	2016
	(in thousands except share and per share amounts)		
Statements of Loss Data:			
Total expenses	$ 12,813	$ 6,632	$ 1,714
Net loss	$ (12,687)	$ (10,583)	$ (1,234)
Basic and diluted loss per common share	$ (3.61)	$ (22.07)	$ (581.25)
Shares used in calculation of net loss per share			
Basic and diluted	3,510,217	479,442	2,123

	December 31,		
	2018	2017	2016
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 14,604	$ 5,284	$ 15
Total assets	$ 19,084	$ 9,892	$ 3,807
Current liabilities	$ 3,270	$ 2,013	$ 3,073
Total liabilities	$ 3,282	$ 2,013	$ 3,197
Additional paid-in capital	$ 41,161	$ 20,556	$ 2,667
Accumulated deficit	$ (25,381)	$ (12,694)	$ (2,062)
Stockholders' equity	$ 15,802	$ 7,879	$ 610

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. The United States Adopted Names, or USAN, Council adopted cytisinicline as the nonproprietary, or generic, name for the substance also known as cytisinicline during the third quarter of 2018. Our focus is to address the global smoking health epidemic, which is a leading cause of preventable death and is responsible for approximately seven million deaths annually worldwide.

Cytisinicline is an established 25-day 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 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 smoking through antagonistic properties. The currently-marketed 1.5 mg cytisinicline dosing schedule reflects that of an anti-addiction medication, with downward dose titration over a period of 25 days.

Investigational New Drug, or IND-enabling, non-clinical toxicology studies completed to date have been sponsored by the National Center for Complementary and Integrative Health, or NCCIH, division of the National Institutes of Health, or NIH, in addition to the National Cancer Institute. In June 2017, we filed our IND application for cytisinicline with the U.S Food and Drug Administration, or FDA, which included NCCIH sponsored non-clinical studies.

In August 2017, we initiated a 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 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. Of the 36 subjects, 24 were to be 18-65 years and 12 were to be greater than 65 years of age. Preliminary results on the 24 smokers (18-65 years) were announced in February 2018 and final results were presented at the annual Society For Research on Nicotine and Tobacco, or SRNT, meeting in February 2019. The study randomized a total of 26 subjects. This included only 2 of the intended 12 subjects greater than age 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 achieving 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 observed were mostly mild with transient headaches as the most commonly reported event. No severe or serious adverse events 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 whether additional drug-to-drug interactions studies will be required prior to any future New Drug Application, or 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 human 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.

A new cytisinicline tablet with improved shelf life has been formulated and recently launched commercially by Sopharma 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 of this new formulation of cytisinicline was well tolerated.

In October 2018, we initiated the ORCA-1 trial, a Phase 2b optimization study in approximately 250 smokers in the United States, or U.S. 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 and potentially other indications. This Phase 2b trial will evaluate both the 1.5 mg and 3.0 mg doses of cytisinicline on a declining titration schedule as well as three times daily dosing, both over 25 days. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. All subjects are treated for 25 days and followed up for a further four weeks. The primary efficacy endpoint is reduction in the number of cigarettes consumed during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 is being conducted at eight centers across the U.S. In February 2019, we announced that the trial had completed enrollment with 254 smokers and top line results are expected in mid-2019.

In December 2018, we announced that 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 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 trial to assess the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. This study will be performed in smokers who will receive one single dose of cytisinicline. The dosage of cytisinicline will be

increased in separate groups of subjects per dose level until stopping criteria (based on the occurrence of dose-limiting adverse events) are reached. This study is a requirement for our future application for marketing approval of cytisinicline.

We previously were developing apatorsen, of which we discontinued further development in August 2017. 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.

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.

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 $12.7 million, $10.6 million and $1.2 million for years end December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $25.4 million, cash, cash equivalents and short term investments balance of $14.6 million and a positive working capital balance of $12.3 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. 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.

The 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.

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. 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. The consolidated results of operations for the year ended December 31, 2016 include only the consolidated results of operations of Achieve and do not include historical results of OncoGenex. 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, 2018, we have 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.

Warrant Liability

The following is a summary of outstanding warrants to purchase common stock that are classified as liabilities at December 31, 2018:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	25,272	$ 440.00	July 2019
(2) Series B Warrants issued in July 2014 financing	6,093	$ 440.00	July 2019

No warrants classified as liabilities were exercised during the years ended December 31, 2018 or 2017.

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.

Results of Operations

Years Ended December 31, 2018, 2017 and 2016

Research and Development Expenses

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

	Year ended December 31,		
	2018	2017	2016
Clinical development programs:			
Cytisinicline	$ 5,868	$ 1,590	$ 286
Other research and development	—	1,511	—
Total research and development expenses	**$ 5,868**	**$ 3,101**	**$ 286**

Research and development expenses for the years ended December 31, 2018, 2017 and 2016 were $5.9 million, $3.1 million and $0.3 million, respectively. 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, a Phase 2b optimization study, 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. The increase in research and development expenses in 2017 as compared to 2016 was due to increased research and development activity for our cytisinicline clinical development program, including the costs associated with filing the IND application, initiating and completing the food effects trial, initiating the repeat dose pharmacokinetics trial and initiating toxicology studies and increased employee expenses and higher facilities costs resulting from the reverse merger of OncoGenex.

General and Administrative Expenses

G&A expenses for the years ended December 31, 2018, 2017 and 2016 were $6.9 million, $3.5 million and $1.4 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. The increase in general and administrative expenses in 2017 as compared to 2016 was due to increase in employee headcount, consulting fees, legal fees and professional fees as a result of the closing of the Arrangement and the integration of OncoGenex with our operations.

Gain / (loss) on warrants

We revalue our warrants classified as liabilities at each balance sheet date to fair value. 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.

Liquidity and Capital Resources

We have incurred an accumulated deficit of $25.4 million through December 31, 2018, 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, 2018, we had a cash, cash equivalents and short term investments balance of $14.6 million and a positive working capital balance of $12.3 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, or 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, 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 is 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 30-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 8,000 shares of common stock with such amounts increasing as the closing sale price of our common stock as reported on The

Nasdaq Capital Market increases. 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 if on the date of a regular purchase the closing sale price of the common stock is not below $20.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 12,352 shares of common stock; no cash proceeds were received from the issuance of these shares. 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 14, 2019, we offered and sold 183,378 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 $3.6 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 Measurement Period, which 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 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 (i) 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 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 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.

From June 19, 2018 to March 14, 2019, 8,579 shares of the Series A Convertible Preferred Stock had been converted into 2,144,750 shares of common stock, and 579 shares of the Series A Convertible Preferred Stock remained outstanding.

From June 19, 2018 through March 14, 2019, 330,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of approximately $1.3 million and 3,119,500 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.

Cash Flows

Operating Activities

For the years ended December 31, 2018, 2017 and 2016, net cash used in operating activities was $10.6 million, $9.1 million, and $0.2 million, respectively. 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. The increase in cash used in operations in 2017 as compared to 2016 was primarily attributable to increased personnel and facilities assumed in the Arrangement, increased research and development expenses for our cytisinicline development program and cash used to reduce liabilities assumed in the Arrangement.

Financing Activities

For the years ended December 31, 2018, 2017 and 2016 net cash provided by financing activities was $19.8 million, $2.0 million and $0.2 million, respectively. 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. Net cash provided by financing activities for the year ended December 31, 2016 related to proceeds from promissory notes payable to a certain shareholder.

Investing Activities

Net cash used in investing activities for the years 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 year ended December 31, 2018 was 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. There were no investing activities for the year ended December 31, 2016.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Seattle office operating lease (1)	$ 317	$ 144	$ 173	$ —	$ —
Vancouver office operating lease (2)	$ 7	$ 7	$ —	$ —	$ —
Vancouver office operating lease (3)	$ 250	$ 56	$ 125	$ 69	$ —
Total	$ 574	$ 207	$ 298	$ 69	$ —

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet financing arrangements at December 31, 2018.

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)	2018	2017
Total Assets	$ 19,084	$ 9,892
Total Liabilities	$ 3,282	$ 2,013
Total Equity	$ 15,802	$ 7,879

The increase in assets as at December 31, 2018 as compared to December 31, 2017 primarily relates to increase in cash and cash equivalents from the June 2018 public offering, the October 2018 registered direct offering and warrant exercises. The increase in liabilities as at December 31, 2018 compared to December 31, 2017 was primarily due to higher accruals related to employee expenses from a full year of operation after the reverse merger with OncoGenex that occurred in August 2017 and higher clinical trial accruals associated with ramp up of the repeat dose pharmacokinetics trial and toxicology studies initiated in late 2017 and initiation of our ORCA-1 trial, a Phase 2b optimization study in October 2018.

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. Under this transition method, compensation cost is recognized in the financial statements beginning with the effective date for all share-based payments granted after January 1, 2006 and for all awards granted prior to but not yet vested as of January 1, 2006. 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 years ended December 31, 2016 and 2015 and 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”, (“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.

Pending Adoption of Recent Accounting Pronouncements

On February 2016, the Financial Accounting Standards Board, or FASB, issued its new leases standard, ASU No. 2016-02, Leases (Topic 842). ASU 2016-02 is aimed at putting most leases on lessees' balance sheets, but it would also change aspects of lessor accounting. ASU 2016-02 is effective for public business entities for annual periods beginning after December 15, 2019 and interim periods within that year. This standard is expected to have an impact on our accounting for our lease arrangements, particularly our current operating lease arrangements, as well as our disclosures. We estimate that the right-of-use asset and lease liability from the adoption of this standard to be approximately $0.5 million.

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 is not expected to have a significant impact on our financial position or results of operations.

Recently Adopted Accounting Policies

In May 2014, the FASB issued 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 principle 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 15 December 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 2017, and interim periods within annual periods beginning after 15 December 2018. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation - Stock Compensation - Improvements to Nonemployee Share-Based Payment Accounting, which both clarifies and modifies accounting requirements relating to nonemployee share-based payment transactions. For public business entities, the amendments in this Update are effective for annual periods beginning after 15 December 2018, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 2019, and interim periods within annual periods beginning after 15 December 2020. 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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and their results of operations and their cash flows for each of the three years in the period ended December 31, 2018 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 14, 2019

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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents *[note 8]*	$ 9,515	$ 5,284
Restricted cash *[note 8 and 14]*	—	222
Short-term investments *[note 8]*	5,089	—
Amounts receivable	7	9
Prepaid expenses	926	393
Total current assets	**15,537**	**5,908**
Restricted cash *[note 8]*	50	50
Property and equipment, net *[note 9]*	35	59
Other assets *[note 10]*	118	309
License agreement *[note 2, 5, 6 and 7]*	2,310	2,532
Goodwill *[note 2 and 6]*	1,034	1,034
Total assets	**$ 19,084**	**$ 9,892**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 144	$ 213
Accrued liabilities other	748	438
Accrued clinical liabilities	1,199	877
Accrued compensation	1,168	458
Current portion of long-term obligations *[note 14]*	11	27
Total current liabilities	**3,270**	**2,013**
Long-term obligations *[note 14]*	12	—
Total liabilities	**3,282**	**2,013**
Commitments and contingencies *[note 14]*		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value, 5,000,000 shares authorized, 579 issued and outstanding at December 31, 2018 and zero issued and outstanding at December 31, 2017.	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized, 6,721,117 and 1,195,675 issued at December 31, 2018 and December 31, 2017, respectively, and 6,721,117 and 1,194,793 outstanding at December 31, 2018 and December 31, 2017, respectively	18	12
Additional paid-in capital	41,161	20,556
Accumulated deficit	(25,381)	(12,694)
Accumulated other comprehensive income	4	5
Total stockholders' equity	**15,802**	**7,879**
Total liabilities and stockholders' equity	**$ 19,084**	**$ 9,892**
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,		
	2018	2017	2016
EXPENSES			
Research and development	$ 5,868	$ 3,101	$ 286
General and administrative	6,945	3,531	1,428
Total operating expenses	12,813	6,632	1,714
OTHER INCOME (EXPENSE)			
Interest income	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	(45)	(35)	(24)
Total other income	126	(7,002)	(24)
Net loss before income taxes	$ (12,687)	$ (13,634)	$ (1,738)
Recovery of deferred income taxes *[note 5]*	—	3,051	504
Net Loss	$ (12,687)	$ (10,583)	$ (1,234)
OTHER COMPREHENSIVE INCOME			
Net unrealized gain on foreign exchange	—	—	4
Total other comprehensive income (loss)	—	—	4
Comprehensive loss	$ (12,687)	$ (10,583)	$ (1,230)
Basic and diluted net loss per common share *[note 12 [g]]*	$ (3.61)	$ (22.07)	$ (581.25)
Shares used in computation of basic and diluted net loss per common share *[note 12 [g]]*	3,510,217	479,442	2,123

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, 2015	2,123	$ —	—	$ —	$ 2,667	$ 1	$ (828)	$ 1,840
Net loss	—	—	—	—	—	—	(1,234)	(1,234)
Other comprehensive income (loss)	—	—	—	—	—	4	—	4
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 preferred shares	2,144,750	2	(8,579)	—	(2)	—	—	—
Net loss	—	—	—	—	—	—	(12,687)	(12,687)
Other comprehensive income (loss)	—	—	—	—	—	(1)	—	(1)
Balance, December 31, 2018	6,721,117	18	579	—	41,161	4	(25,381)	15,802

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating Activities:			
Net loss	$ (12,687)	$ (10,583)	$ (1,234)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on warrants *[note 8 and note 12[e]]*	—	(150)	—
Depreciation	60	59	—
Amortization	222	223	223
Stock-based compensation *[note12[c]]*	854	348	—
Deferred income tax (recovery) *[note 2 and 5]*	—	(3,051)	(504)
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	2	(9)	—
Prepaid expenses and other assets	(343)	(1,349)	(2)
Accounts payable	(69)	118	22
Accrued liabilities other	310	(2,185)	670
Accrued clinical liabilities	322	877	—
Accrued compensation	710	458	—
Salaries payable	—	(1,028)	623
Lease obligation	(4)	27	—
Net cash used in operating activities	(10,623)	(9,107)	(202)
Financing Activities:			
Proceeds from share subscription	—	64	—
Proceeds from purchase agreement with Lincoln Park Capital, net of issuance costs	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	1,324	—	—
Proceeds from October 2018 registered direct offering, net of issuance costs	4,960	—	—
Taxes paid related to net share settlement of equity awards	—	(5)	—
Stockholder loans	—	—	150
Net cash provided by financing activities	19,757	2,001	150
Investing Activities:			
Cash received on reverse takeover of OncoGenex	—	12,648	—
Purchase of property and equipment	(46)	—	—
Proceeds on disposal of assets	10	—	—
Purchase of investments	(5,539)	—	—
Maturities of investments	450	—	—
Net cash provided by (used in) investing activities	(5,125)	12,648	—
Effect of exchange rate changes on cash	—	(1)	—
Net increase (decrease) in cash, cash equivalents and restricted cash	4,009	5,541	(52)
Cash, cash equivalents and restricted cash at beginning of year	5,556	15	67
Cash, cash equivalents and restricted cash at end of year	$ 9,565	$ 5,556	$ 15
Supplemental Disclosure of Cash Flow Information:			
Interest expense accrued but not yet paid	$ —	$ —	$ 26

See accompanying notes.

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

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. The consolidated results of operations for the year ended December 31, 2016 include only the consolidated results of operations of Achieve and do not include historical results of OncoGenex. 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. The accompanying consolidated Balance Sheet at December 31, 2016 has been derived from the audited consolidated financial statements included in our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the Securities and Exchange Commission, or SEC, on June 6, 2017. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC on June 6, 2017.

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.

Liquidity

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 $12.7 million, $10.6 million and $1.2 million for the years ending December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $25.4 million, cash, cash equivalents and short term investments balance of $14.6 million and a positive working capital balance of $12.3 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.

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.

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 12—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 occurs, 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 common shares, 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. The consolidated results of operations for twelve months ended December 31, 2016 include only our consolidated results of operations and do not include historical results of OncoGenex.

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, 2018 (Unaudited)	For the year ended December 31, 2017 (Unaudited)
Revenue	$ —	$ —
Net loss applicable to common shareholders	$ (12,687)	$ (20,111)
Net loss per share-basic and diluted	$ (3.61)	$ (41.95)
Weighted average shares	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. Under this transition method, compensation cost is recognized in the financial statements beginning with the effective date for all share-based payments granted after January 1, 2006 and for all awards granted prior to but not yet vested as of January 1, 2006. 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 years ended December 31, 2016 and 2015 and 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.

Pending Adoption of Recent Accounting Pronouncements

On February 2016, the Financial Accounting Standards Board, or FASB, issued its new leases standard, ASU No. 2016-02, Leases (Topic 842). ASU 2016-02 is aimed at putting most leases on lessees' balance sheets, but it would also change aspects of lessor accounting. ASU 2016-02 is effective for public business entities for annual periods beginning after December 15, 2019 and interim periods within that year. This standard is expected to have an impact on our accounting for our lease arrangements, particularly our current operating lease arrangements, as well as our disclosures. We estimate that the right-of-use asset and lease liability from the adoption of this standard to be approximately $0.5 million.

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 is not expected to have a significant impact on our financial position or results of operations.

Recently Adopted Accounting Policies

In May 2014, the FASB issued 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 principle 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 15 December 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 2017, and interim periods within annual periods beginning after 15 December 2018. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation - Stock Compensation - Improvements to Nonemployee Share-Based Payment Accounting, which both clarifies and modifies accounting requirements relating to nonemployee share-based payment transactions. For public business entities, the amendments in this Update are effective for annual periods beginning after 15 December 2018, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 2019, and interim periods within annual periods beginning after 15 December 2020. 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, 2018 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. The agreements were determined to have a fair value of $3.1 million with an estimated useful life of 14 years (Note 6— Extab Acquisition).

The components of intangible assets were as follows:

	December 31, 2018			December 31, 2017		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (807)	$ 2,310	$ 3,117	$ (585)	$ 2,532

For the year ended December 31, 2018 and 2017 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, 2018:

Year Ending December 31,	
2019	223
2020	223
2021	223
2022	223
Thereafter	1,418
Total	**$ 2,310**

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, 2018.

6. EXTAB ACQUISITION

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma, AD, or Sopharma, a public pharmaceutical company located in Bulgaria, to acquire 75% of the outstanding shares of Extab.

Pursuant to the Share Purchase Agreement, we acquired a 75% controlling interest in Extab from Sopharma for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA. In addition, as part of and in conjunction with the Share Purchase Agreement, we amended our existing license and supply agreements with Sopharma, extending their terms by five years and reducing the royalty rate payable by us. (Note 7—License Agreements) Subsequent to the acquisition, we paid to Sopharma $0.3 million to retire the balance of Extab's outstanding loans with Sopharma.

The acquisition was accounted for using the acquisition method under ASC 805 business combinations. Results of operations have been included in the financial statements from the date of acquisition May 18, 2015, the date we assumed control of Extab. The fair value of the business combination was determined using level 3 inputs.

The purchase price of our 75% controlling interest in Extab was as follows:

Cash consideration	$	2,000
Contingent consideration		—
Purchase Price	**$**	**2,000**

As of the date of acquisition we assessed the likelihood of meeting the contingent event as unlikely and as a result have estimated its fair value at zero. We consider the best indicator of the fair value of net assets acquired to be the $2.0 million cash consideration paid to acquire our 75% controlling interest plus the $0.7 million fair value attributable to the non-controlling interest, or NCI, calculated on a proportionate basis.

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities of Extab based on their estimated fair values as of the transaction closing date. The allocation of the purchase price based on the estimated fair values is as follows:

		Fair Value
Cash	$	6
License agreements	$	3,117
Goodwill	$	1,034
Other current liabilities	$	(456)
Deferred tax liability	$	(1,034)
Non-controlling interest	$	(667)
	$	**2,000**

The license agreement expires May 26, 2029. As of the acquisition date, we estimated its useful life to be the same as the remaining 14 year contractual life. We also elected to amortize intangible assets on a straight line basis over its useful life, since there is no pattern of successful economic benefits available at the time to reliably determine a different amortization.

Subsequent to acquiring control of Extab, we entered into an agreement with the NCI stockholder of Extab to convert their shares in Extab into shares of our common stock. As of September 30, 2015, all of the NCI had converted their shares in Extab into shares of our common stock resulting in elimination of the Extab non-controlling interest and Extab becoming a wholly-owned subsidiary of us.

7. 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, Achieve 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, 2018, we have 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 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.

8. 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

As of December 31, 2018, we recorded a value of zero for our warrant liability. 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.

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, 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 12)	50	—	—	50
Corporate bonds and commercial paper (short term investments)	—	5,089	—	5,089
Total assets	**$ 9,565**	**$ 5,089**	**$ —**	**$ 14,654**

December 31, 2017	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 1,262	$ —	$ —	$ 1,262
Money market securities (cash equivalents)	4,022	—	—	4,022
Restricted cash (Note 12)	272	—	—	272
Total assets	$ 5,556	$ —	$ —	$ 5,556

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

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

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,262	$ —	$ —	$ 1,262
Money market securities	4,022	—	—	4,022
Total cash and cash equivalents	$ 5,284	$ —	$ —	$ 5,284
Money market securities (restricted cash)	272	—	—	272
Total restricted cash	$ 272	$ —	$ —	$ 272

Our gross realized gains and losses on sales of available-for-sale securities were not material for the years ended December 31, 2018 and 2017.

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, 2018, given the quality of the investment portfolio, its short-term nature, and subsequent proceeds collected on sale of securities that reached maturity.

9. PROPERTY AND EQUIPMENT

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

	Cost	Accumulated Depreciation	Net Book Value
December 31, 2018			
Computer equipment	$ 258	$ 230	$ 28
Furniture and fixtures	90	90	—
Leasehold improvements	55	53	2
Computer software	328	323	5
Equipment under capital lease	24	24	—
Total property and equipment	$ 755	$ 720	$ 35

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.

10. 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.

11. 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, 2018, 2017 and 2016 of 21%, 34% 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)	2018	2017	2016
Income taxes at statutory rates (at a rate of 21% for 2018 and 34% for 2017 and 2016)	$ (2,664)	$ (4,636)	$ (504)
Expenses not deducted for tax purposes	70	(174)	—
Effect of tax rate changes on deferred tax assets and liabilities	(1,416)	3,158	—
Rate differential on foreign earnings	(165)	314	—
Reduction in benefit of operating losses	—	—	—
Reduction in the benefit of other tax attributes	—	—	—
Investment tax credits	—	—	—
Change in valuation allowance	4,182	(1,683)	—
Book to tax return adjustments	20	—	—
Other	(27)	(14)	—
Income tax expense	$ —	$ (3,035)	$ (504)

[b] At December 31, 2018, we have investment tax credits of $2.6 million (2017—$2.6 million) available to reduce future Canadian income taxes otherwise payable. We also have non-capital loss carryforwards of $123.3 million (2017—$120.4 million) available to offset future taxable income in Canada, UK net operating loss carryforwards of $1.8 million (2017—$0.8 million) to offset future taxable income in the UK and federal net operating loss carryforwards of $17.6 million (2017—$9.9 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	—	—	—	—
2023	—	—	—	—
2024	—	—	—	—
2025	—	—	—	—
2026	244	—	7,364	—
2027	71	—	4,949	—
2028	148	—	8,020	—
2029	317	9	(9)	33
2030	346	5	6,288	20
2031	486	17	12,121	34
2032	363	43	17,278	41
2033	193	2	23,240	53
2034	215	3	17,077	45
2035	122	654	3,112	27
2036	79	611	16,664	56
2037	19	8,763	4,254	633
2038	52	7,491	2,937	887
	$ 2,655	$ 17,598	$ 123,295	$ 1,829

In addition, we have unclaimed tax deductions of approximately $14.5 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 $0.1 million available to reduce future taxes payable in the United States. The research and development tax credits expire in 2038.

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

	2018	2017
Deferred tax assets		
Tax basis in excess of book value of assets	$ 886	$ 850
Non-capital loss carryforwards	37,332	33,524
Research and development deductions and credits	5,707	5,506
Stock options	171	51
§59(e) Capitalized R&D expenses	3,334	3,252
Accrued expenses	—	—
Other	170	246
Total deferred tax assets	47,600	43,429
Valuation allowance	(47,123)	(42,914)
Net deferred assets	477	515
Deferred tax liabilities		
Intangible assets	(474)	(513)
Other	(3)	(2)
Total deferred tax liabilities	(477)	(515)
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, 2018.

[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, 2018 is as follows (in thousands):

	Year ended December 31,		
	2018	2017	2016
Balance at January 1	$ 715	$ 715	$ 699
Additions based on tax positions related to the current year	6	—	16
Deductions based on tax positions related to prior years	(4)	—	—
Balance at December 31	$ 717	$ 715	$ 715

As of December 31, 2018, 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, 2018 and December 31, 2017 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	2010 to 2018
United Kingdom	2011 to 2018
US	2010 to 2018

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.

12. 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, or 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 is 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 30-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 8,000 shares of common stock with such amounts increasing as the closing sale price of our common stock as reported on The Nasdaq Capital Market increases. 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 if on the date of a regular purchase the closing sale price of the common stock is not below $20.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 12,352 shares of common stock; no cash proceeds were received from the issuance of these shares. 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 December 31, 2018, we offered and sold 183,378 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 $3.6 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 Measurement Period, which 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 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 (i) 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 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 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, 2018, 8,579 shares of the Series A Convertible Preferred Stock had been converted into 2,144,750 shares of common stock, and 579 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 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.

Equity Award Issuances and Settlements

During the year ended December 31, 2018, we did not issue any shares of common stock to satisfy stock option exercises and issued 5,354 shares of common stock to satisfy restricted stock unit settlements, respectively, compared with the issuance of no shares of common to satisfy stock option exercises and 546 restricted stock unit settlements, respectively, for the year ended December 31, 2017.

[c] Stock options

2018 Equity Incentive Plan

As of December 31, 2018, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 1,000,000 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 386,650 were reserved for options currently outstanding and 613,350 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, 2018, 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, 2018, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 21,065 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 15,142 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:

	2018	2017
Risk-free interest rates	2.93%	1.95%
Expected dividend yield	0%	0%
Expected life	5.68 years	6.02 years
Expected volatility	88.23%	86.06%

The weighted average fair value of stock options granted during the year ended December 31, 2018 was $2.05.

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,	
	2018	2017
Research and development	$ 272	$ 107
General and administrative	582	241
Total stock-based compensation	$ 854	$ 348

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, 2018	**111,578**	$ 80.01
Granted	554,400	2.81
Forfeited	(393)	160.79
Balance, December 31, 2018	**665,585**	**$ 15.65**

The following table summarizes information about stock options outstanding at December 31, 2018 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)
$2.56 - $2.97	386,650	$ 2.56	9.72
$2.98 - $16.13	167,750	3.37	9.57
$16.14 - $69.45	104,910	28.90	8.58
$69.46 - $157.30	408	110.00	7.40
$157.31 - $206.25	1,782	204.60	6.38
$206.26 - $1,228.15	835	448.47	5.53
$1,228.16 - $1,305.70	907	1,296.49	5.15
$1,305.71 - $1,405.80	713	1,321.28	4.12
$1,405.81 - $1,659.35	605	1,443.12	3.21
$1,659.36 - $2,450.80	1,025	2,007.37	1.65
	665,585	**$ 15.65**	**9.46**

(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)
$2.56 - $2.97	35,417	$ 2.56	9.72
$2.98 - $16.13	17,472	3.37	9.57
$16.14 - $69.45	37,488	28.90	8.58
$69.46 - $157.30	408	110.00	7.40
$157.31 - $206.25	1,745	204.60	6.38
$206.26 - $1,228.15	835	448.47	5.53
$1,228.16 - $1,305.70	907	1,296.49	5.15
$1,305.71 - $1,405.80	713	1,321.28	4.12
$1,405.81 - $1,659.35	605	1,443.12	3.21
$1,659.36 - $2,450.80	1,025	2,007.37	1.65
	96,615	**$ 73.05**	**8.94**

As at December 31, 2018, and December 31, 2017 the total unrecognized compensation expense related to stock options granted was $2.4 million and $2.0 million respectively, which is expected to be recognized into expense over a period of approximately 2.9 years.

The estimated grant date fair value of stock options vested during the years ended December 31, 2018, 2017 and 2016 was $1.0 million, $0.6 million and zero, 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, 2018, 2017 and 2016 was zero, zero and zero, respectively. At December 31, 2018, 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, 2018, 2017 and 2016, $0.2 million, $0.1 million and zero, 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, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, January 1, 2018	**21,066**	**$ 38.87**
Released	(5,354)	56.25
Forfeited or expired	(570)	97.03
Balance, December 31, 2018	**15,142**	**$ 30.53**

As of December 31, 2018, we had approximately $0.4 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 2.58 years.

[e] Stock Warrants

The following is a summary of outstanding warrants to purchase common stock at December 31, 2018:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	25,272	$ 440.00	July 2019
(2) Series B Warrants issued in July 2014 financing	6,093	$ 440.00	July 2019
(3) Series A-1 Warrants issued in April 2015 financing	2,175	$ 264.00	October 2020
(4) Warrants issued in September 2017 financing	8,224	$ 34.96	March 2023
(5) Warrants issued in June 2018 financing	3,119,500	$ 4.00	June 2023
(6) Warrants issued in October 2018 financing	894,626	$ 3.14	October 2023

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. The Series A-1 Warrants assumed by us as part of the Arrangement, the warrants issued in the September 2017 financing, the warrants issued in the June 2018 financing and the warrants issued in the October 2018 registered direct offering, are classified as equity. The Series A and Series B warrants assumed by us as part of the Arrangement are classified as liabilities. The estimated fair value of warrants classified as liabilities is reassessed at each reporting date using the Black-Scholes pricing model. As at December 31, 2018 and 2017, the fair value of the warrants was insignificant.

Series A and Series B Warrant Valuation Assumptions	As of December 31, 2018	2017
Risk-free interest rates	2.61%	1.82%
Expected dividend yield	0%	0%
Expected life	0.50 years	1.50 years
Expected volatility	111%	86%

[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, 2018	2017	2016
Numerator			
Net loss	$ (12,687)	$ (10,583)	$ (1,234)
Denominator			
Weighted average number of common shares outstanding	3,510,217	479,442	2,123
Basic and diluted net loss per common share	$ (3.61)	$ (22.07)	$ (581.25)

As of December 31, 2018 a total of 4.7 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.

13. 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. As of December 31, 2016, we recorded amounts payable to Ricanto of $0.6 million in accrued liabilities on our balance sheet. 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, par value $0.01. 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, 2018 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%. As of December 31, 2016 the outstanding principal, included in shareholder loans with related parties, was $0.2 million and accrued interest payable was $3,000. 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, par value $0.01. 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, 2018 we had no outstanding principal or accrued interest with the related party.

We borrowed $2.7 million on May 18, 2015, through a convertible promissory note payable to a Lender of ours. The note matures and is payable upon demand one year from the date of the note. Interest accrues at an annual rate of 3.5%. On September 30, 2015 the Lender converted $2.0 million in principal into 4,500 shares of our common stock, prior to the closing of the Arrangement, par value

$0.01, and became a principal stockholder. On March 7, 2017 we borrowed $20,000 through a note payable to the Lender. The note matures and is payable upon demand one year from the date of issuance. Interest accrues at an annual rate of 3.5%. As of December 31, 2016, the outstanding principal balance, included in shareholder loans with related parties, was $0.7 million and had accrued interest payable of $35,000. 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, par value $0.01. 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, 2018 we had no outstanding principal or accrued interest with the related party.

We entered into an employment agreement on May 11, 2015 with one of our principal stockholders to serve as our CEO. We terminated the employment agreement on December 31, 2016. From May 11, 2015 to December 31, 2016, we had not paid any salary specified in the employment agreement. Salary otherwise payable as at December 31, 2016 was $0.7 million and was accrued on our balance sheet as Accrued compensation. 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, 2018 we had no outstanding principal or accrued interest with the related party.

We entered into an employment agreement on August 17, 2015 with one of our principal stockholders to serve as our Chief Financial Officer, or CFO. We terminated the employment agreement on December 31, 2016. From August 17, 2015 to December 31, 2016, we had not paid any salary specified in the employment agreement. Salary otherwise payable as at December 31, 2016 was $0.3 million and was accrued on our balance sheet as Accrued compensation. 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, 2018 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, 2018.

14. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Seattle office operating lease	$ 317	$ 144	$ 173	$ —	$ —
Vancouver office operating lease - expiring	$ 7	$ 7	$ —	$ —	$ —
Vancouver office operating lease - new	$ 250	$ 56	$ 125	$ 69	$ —
Total	$ 574	$ 207	$ 298	$ 69	$ —

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 provide 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):

2019	$	56
2020		62
2021		63
2022		63
2023		5
Total	**$**	**249**

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 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):

2019	$	144
2020		148
2021		25
Total	**$**	**317**

Consolidated rent and operating expense relating to both the Vancouver, Canada and Seattle, Washington, and Bothell, Washington offices for years ended December 31, 2018, 2017 and 2016 was $0.3 million, $0.6 million and $0.9 million, respectively.

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, 2018.

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, 2018	2017
Total Assets	$ 19,084	$ 9,892
Total Liabilities	3,282	2,013
Total Equity	15,802	7,879

The increase in assets as at December 31, 2018 as compared to December 31, 2017 primarily relates to increase in cash and cash equivalents from the June 2018 public offering, the October 2018 registered direct offering and warrant exercises. The increase in liabilities as at December 31, 2018 compared to December 31, 2017 was primarily due to higher accruals related to employee expenses from a full year of operation after the reverse merger with OncoGenex that occurred in August 2017 and higher clinical trial accruals associated with ramp up of the repeat dose pharmacokinetics trial and toxicology studies initiated in late 2017 and initiation of our ORCA-1 trial, a Phase 2b optimization study in October 2018

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15. 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 4—Intangibles). The severance payable was settled following the completion of the Arrangement and no amounts were owing as at December 31, 2018.

16. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes the unaudited statements of operations for each quarter of 2018 and 2017 (in thousands, except per share amounts):

	March 31	June 30	September 30	December 31
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)
2017				
Research and development	61	62	825	2,153
General and administrative	260	96	1,546	1,629
Total operating expenses	321	158	2,371	3,782
Other income	(8)	(11)	(7,025)	42
Recovery of deferred income taxes	124	—	2,927	—
Net loss	(205)	(169)	(6,469)	(3,740)
Basic and diluted net loss per share	$ (96.56)	$ (79.60)	$ (8.95)	$ (3.17)

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 the end of the period covered by this Annual Report on Form 10-K.

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, 2018 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, 2018, 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, 2018.

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

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth in our 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018, 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018, 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, 2018:

	(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	680,727	(1)	$ 15.65	(1)	613,350	(1)
Equity compensation plans not approved by security holders	—		—		—	
Total	680,727		$ 15.65		613,350	

(1) As of December 31, 2018, 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018, 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018, 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 A Convertible Preferred Stock, filed June 18, 2018	8-K	033-80623	3.1	June 20, 2018	
3.9	Sixth Amended and Restated Bylaws	8-K	033-80623	3.1	January 5, 2017	
3.10	Amendment to Sixth Amended and Restated Bylaws	10-Q	033-80623	3.1	November 7, 2018	
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	
10.1	Sonus Pharmaceuticals, Inc. 2007 Performance Incentive Plan (the “2007 Plan”)††	DEF 14A	000-21243	Appendix A	April 3, 2007	
10.2	Form of Sonus Pharmaceuticals, Inc. Stock Option Agreement (pertaining to the 2007 Plan)††	10-Q	000-21243	10.1	November 9, 2007	
10.3	OncoGenex Technologies Inc. Amended and Restated Stock Option Plan††	F-1	333-139293	10.1	December 13, 2006	
10.4	Form of OncoGenex Pharmaceuticals, Inc. 2010 Stock Option Agreement††	8-K	033-80623	10.1	June 14, 2010	
10.5	Form of OncoGenex Pharmaceuticals, Inc. 2010 Restricted Stock Unit Agreement††	10-Q	033-80623	10.2	November 3, 2011	
10.6	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated††	DEF 14A	033-80623	Appendix A	April 16, 2015	
10.7a	Achieve Life Sciences 2017 Equity Incentive Plan††	DEF 14A	033-80623	Appendix A	September 21, 2017	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.7b	Form of Achieve Life Sciences Stock Option Agreement††	10-Q	033-80623	10.7b	March 1, 2018	
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	10.22	
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.						X
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	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		
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
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

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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.

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

** 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 14, 2019

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 14, 2019
By: /s/ JOHN BENCICH John Bencich	Executive Vice President, Chief Financial Officer and Chief Operating Officer	Date: March 14, 2019
By: /s/ ANTHONY CLARKE Anthony Clarke	Director	Date: March 14, 2019
By: /s/ SCOTT CORMACK Scott Cormack	Director	Date: March 14, 2019
By: /s/ DONALD JOSEPH Donald Joseph	Director	Date: March 14, 2019
By: /s/ MARTIN MATTINGLY Martin Mattingly	Director	Date: March 14, 2019
By: /s/ H. STEWART PARKER H. Stewart Parker	Director	Date: March 14, 2019
By: /s/ JAY MOYES Jay Moyes	Director	Date: March 14, 2019

THE GROSVENOR BUILDING

1040 WEST GEORGIA STREET

VANCOUVER, B.C.

OFFICE LEASE

0846869 B.C. LTD.

TO

ACHIEVE LIFE SCIENCES TECHNOLOGIES INC.

THE GROSVENOR BUILDING
1040 West Georgia Street

OFFICE LEASE

INDEX

THE GROSVENOR BUILDING
OFFICE LEASE

THIS LEASE made and entered into this 19th day of November, 2018.

BY AND BETWEEN:

0846869 BC Ltd., whose principal place of business and post office address is 520-701 West Georgia Street, Vancouver, British Columbia V7Y 1A1

(herein called the "Landlord")

AND:

ACHIEVE LIFE SCIENCES TECHNOLOGIES INC. whose principal place of business and post office address is 1030 – 1040 West Georgia, Vancouver, BC

(herein called the "Tenant")

WITNESSES THAT in consideration of the demise herein contained and the covenants and agreements herein contained and for certain other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged by each of the parties hereto, it is hereby agreed as follows:

1. SUMMARY

1.1 Particulars of Lease

The parties acknowledge that the following summarizes certain matters relevant to this Lease. The following summary does not limit the meaning of any other provision of this Lease. If any other provision of this Lease is inconsistent with the following summary, the other provisions of this Lease will prevail. The Tenant acknowledges that it does not rely on estimates set forth in this subarticle 1.1.

(a) Premises: **Suite 1030 on Tenth (10) Floor;**

(b) Premises Rentable Area: **approximately 2,367 square feet**;

(c) Building Rentable Area: **approximately 203,766 square feet**;

(d) Tenant's Percentage Share: **approximately 1.16%**;

(e) Term: **FOUR (4) Years, *Zero (0)* Months and Zero (0) Days**, commencing on the Commencement Date and continuing to and including the Expiration Date;

(f) Commencement Date: **February 1, 2019**;

(g) Expiration Date: **January 31, 2023**;

(h) Possession Date for Alterations, etc. (Schedule C Article 4): **January 1, 2019**;

(i) Rent Commencement Date: **February 1, 2019**;

(j) Annual Base Rent:

Years	***per square foot per annum***	***Annual***
Years 1-2	***$ 35.50***	***$ 84,028.50***
Years 3-4	***$ 36.50***	***$ 86,395.50***

(k) Monthly Base Rent:

YearsMonthly
Years 1-2$ 7,002.38
Years 3-4 $ 7,199.63

(l) Rent Adjustment Dates: ***February 1, 2021***;

(m) Security Deposit: $24,770.66 (Article 7)

(n) Use of Premises restricted to: ***General Business Offices***;

(o) Tenant's Address for Notices: At the Premises

(Subject to change as provided in Article 26.)

(p) Landlord's Address for Notices:

Attention: Mr. Segal
0846869 B.C. Ltd.
Ste. 520-701West Georgia Street
Vancouver, B.C. V7Y 1A1
*Fax: 604-687-6539

with a copy to:

SDM Realty Advisors Ltd.
Suite 1850 - 1040 West Georgia Street
Vancouver, B.C. V6E 4H1
*Fax: 604-688-5669

(Subject to change as provided in Article 26.)

(q) Tenant's Estimated Annual Share of Operating Expenses for the year 2018 (being $15.07 per square foot of Premises Rentable Area) $35,670.69;

(r) Tenant's Estimated Annual Share of Taxes for the year 2018 (being $8.73 per square foot of Premises Rentable Area) $20,663.91.

1.2 Defined Terms

The following words and phrases, when used in this Lease, will have the meanings ascribed to them in or pursuant to this Article; and plural forms of the following words and phrases shall have corresponding meanings.

(a) "Additional Rent" means any and all amounts payable under this Lease by the Tenant to the Landlord other than Annual Base Rent and Percentage Rent;

(b) "Annual Base Rent" means the amount specified in subarticle 1.1(j) as adjusted on the Rent Adjustment Dates, if any;

(c) "Alterations" has the meaning ascribed in subarticle 10.1;

(d) "Building" means the office building situate on the Lands and known as The Grosvenor Building situate at 1040 West Georgia Street, Vancouver, British Columbia including without limitation parking facilities, plazas, landscaping and ornamentation, plants, fixtures, machinery and equipment relating thereto and the lands upon which the foregoing are constructed or installed and any structures, equipment or facilities, over or under adjacent streets and lanes constructed or installed by or for the Landlord in connection with the Building;

(e) "Building Rentable Area" shall be determined in accordance with articles 2.3 and 2.4;

(f) "Building Systems" has the meaning ascribed thereto in subarticle 27.17 hereof;

(g) "Common Areas" has the meaning ascribed thereto in subarticle 9.1;

(h) "Commencement Date" means the date specified in subarticle 1.1(f) or such other date as may be determined pursuant to subarticle 3.2;

(i) "Expiration Date" means the date specified in subarticle 1.1(g);

(j) "Goods and Services Tax" has the meaning ascribed thereto in subarticle 6.14;

(k) "High Consumption Equipment" has the meaning ascribed thereto in subarticle 9.1(b);

(l) "HVAC" and "HVAC Systems" have the meaning ascribed thereto respectively in subarticle 9.1(a);

(m) "Lands" means the lands particularly described in Schedule "A";

(n) "Operating Expenses" has the meaning ascribed thereto in subarticle 6.3;

(o) "Ordinary Business Hours" means the hours so designated from time to time by the rules and regulations under subarticle 8.7;

(p) "Possession Date" means the date specified in subarticle 1.1(h);

(q) "Premises" means those parts of the Building situate on the floor(s) designated in subarticle 1.1(a) and shown hatched on Schedule "A" hereto except Building Systems and any areas excluded by subarticle 27.17; and the boundaries of the Premises are more particularly set forth in subarticle 27.17 hereof;

(r) "Premises Rentable Area" shall be determined in accordance with articles 2.3 and 2.4;

(s) "Prime Rate" means the annual rate of interest designated by the Royal Bank of Canada as its bank as being its Prime Rate for demand loans made in lawful money of Canada in Canada;

(t) "Rent" means all amounts payable under this Lease by the Tenant to the Landlord;

(u) Each of the dates specified in subarticle 1.1(l) is a "Rent Adjustment Date";

(v) "Rent Adjustment Period" has the meaning ascribed thereto in subarticle 5.1;

(w) The "Rentable Area" of any part of the Building or of the Premises shall be determined in accordance with subarticle 2.4;

(x) "Rules and Regulations" has the meaning ascribed thereto in subarticle 8.7;

(y) "Special Tenant Expenses" means the amounts payable by the Tenant under subarticle 6.7 hereof;

(z) "Taxes" has the meaning ascribed thereto in subarticle 6.10;

(aa) [Reserved]

(bb) "Tenant's Percentage Share" has the meaning ascribed thereto in subarticle 6.5;

(cc) "Tenant's Taxes" has the meaning ascribed thereto in subarticle 6.12;

(dd) "Term" means the period stated in subarticle 1.1(e); and

(ee) "Year" means a period of 12 months commencing on January 1 and ending on December 31.

Reference herein to a person includes reference to a corporation or any other legal entity.

2. PREMISES

2.1 Demise

The Landlord hereby leases the Premises to the Tenant and the Tenant hereby takes and leases the Premises from the Landlord for the Term and subject to the covenants, agreements, conditions and provisions herein contained reserving always unto the Landlord Rent as herein provided.

2.2 License

The Landlord hereby grants to the Tenant a license to use, in common with the Landlord and others from time to time authorized by the Landlord, the washrooms on any floor of the Building on which the Tenant is a partial floor tenant and the loading dock and those lobbies, corridors, stairways and

elevators from time to time designated by the Landlord and required for the purpose of access to and egress from the Premises, but only in accordance with the Rules and Regulations.

2.3 Rentable Areas - Estimated

The Building Rentable Area and the Premises Rentable Area shall be determined by the Landlord for the purpose of this Lease. If the Building Rentable Area and the Premises Rentable Area or either of them could not be accurately calculated prior to the execution of this Lease they may be estimated by the Landlord and, when they are accurately calculated:

(a) if the estimate previously made was not correct or has changed, the appropriate adjustments shall be made, retroactively to the commencement of the Term, to the Rent payable under this Lease, and

(b) the parties hereto will enter into an agreement in writing supplemental to this Lease stating the adjusted Premises Rentable Area and any adjusted Building Rentable Area and any adjusted amounts of Rent and any adjusted Tenant's Percentage Share. Such agreement shall be in the form reasonably required by the Landlord.

2.4 Rentable Areas - Correction or Adjustment

The Landlord may from time to time calculate or recalculate or measure or remeasure any one or more of the following in accordance with methods then considered to be good practice for comparable buildings and premises: the Building Rentable Area; the Premises Rentable Area; and the rentable area of any part of the Building. If the Building Rentable Area or the Premises Rentable Area are determined to be different from those stated herein or in any instrument supplemental hereto entered into from time to time then:

(a) the Tenant's Percentage Share will be adjusted accordingly with effect as at the date upon which the Landlord shall give notice of the change to the Tenant; and

(b) the parties hereto will enter into an agreement supplemental to this Lease stating the recalculated or remeasured Building Rentable Area and Premises Rentable Area and the adjusted Tenants' Percentage Share; and

(c) in the event that and to the extent that the recalculation or remeasurement of the Premises Rentable Area determines that an error was made in the estimation or calculation of the Premises Rentable Area, such agreement supplemental hereto shall state the adjusted amounts of Rent payable hereunder with effect as at the date upon which the Landlord shall give written notice of such error to the Tenant.

Upon determining that an error exists in the calculation of the Building Rentable Area or the Premises Rentable Area the Landlord will promptly give notice of that error to the Tenant and the foregoing provisions of this subarticle 2.4 shall apply with necessary changes.

3. POSSESSION

3.1 Possession for Alterations, etc.

The Landlord will use all reasonable efforts to give the Tenant possession of the Premises on the Possession Date for the purpose of installation and construction of the Tenant's Alterations or such other purposes as the Landlord may approve; but such possession may be in conjunction with the Landlord and its contractors and others authorized by the Landlord. The Landlord will attempt to ensure that, during the period from the Possession Date until the Commencement Date, others entitled to occupy the Premises in conjunction with the Tenant will co-operate with the Tenant and its contractors. At any time the Tenant is permitted to have occupancy of the Premises prior to the Commencement Date, whether exclusively or in common with the Landlord, its contractors, sub-contractors or employees, the Tenant shall, to the extent applicable, be subject to and comply with all terms, covenants and conditions of this Lease except that no Annual Base Rent, Tenant's Percentage Share of Operating Expenses, or Tenant's Percentage Share of Taxes shall be payable by the Tenant for the period prior to the Commencement Date.

3.2 Delay in the Commencement Date

If the Landlord is unable to deliver exclusive possession of the Premises to the Tenant at the Commencement Date stated in subarticle 1.1(f), the Landlord shall not be liable for any damage resulting therefrom and this Lease shall not be rendered void or voidable thereby, but the Tenant shall not be liable for any Rent or other amount referred to in subarticle 4.1 until such time as the Landlord does deliver exclusive possession of the Premises to the Tenant. No failure to tender possession on the Commencement Date so stated shall:

(a) in any way affect any other obligations of the Tenant; or

(b) extend the Termination Date;

but the commencement of the Term shall be postponed until the day upon which the Landlord does deliver exclusive possession of the Premises. The Landlord and the Tenant shall then promptly execute an amendment to this Lease in such form as the Landlord may reasonably require stating the new Commencement Date and the length of the Term.

3.3 Condition of the Premises

The Tenant's taking possession of the Premises shall constitute the Tenant's acknowledgement that the Premises are in good order and in good and tenantable condition.

4. RENT

4.1 Reservation and Covenant to Pay

The Landlord hereby reserves unto itself and the Tenant hereby covenants and agrees to pay to the Landlord without set-off, abatement or deduction save as expressly set out herein, in each year of the Term in lawful money of Canada the aggregate of the following:

(a) the Annual Base Rent subject to adjustment in accordance with subarticle 5.1; plus

(b) the Tenant's Percentage Share of Operating Expenses

all of which shall be paid in equal monthly instalments in advance on the first day of each calendar month in each calendar year; plus

(c) the Tenant's Percentage Share of Taxes which shall be paid in each year in accordance with subarticle 6.8; plus

(d) Special Tenant Expenses provided for in subarticle 6.7 which shall be paid forthwith upon delivery of an invoice therefor by the Landlord to the Tenant.

The Tenant acknowledges and agrees that the Landlord shall have the right to require the Tenant to pay to the Landlord the amount of the Goods and Services Tax on any payments of Rent under this Lease and the Tenant covenants and agrees to pay to the Landlord the amount of the Goods and Services Tax on any payments of Rent under this Lease at the same time as the amounts to which the Goods and Services Tax apply are payable to the Landlord under this Lease, or upon demand at such other time or times as the Landlord may from time to time determine.

4.2 Payment

All payments required to be made by the Tenant under this Lease, save as expressly set out herein, shall be made without any set-off, abatement, deduction or counterclaim whatsoever and shall be made payable to and delivered to the Landlord at the office of the Landlord in the Building or such other place in Canada as the Landlord may designate. The Tenant shall deliver to the Landlord at the beginning of each year throughout the Term and upon any change of bank by the Landlord an authorization for payments to be made to the Landlord by automatic bank transfer or other method acceptable to the Landlord from time to time for each of the monthly instalments of Rent payable under subarticles 4.1(a), (b) and (c); provided that the Tenant may, in lieu of authorized automatic bank transfers, deliver to the Landlord a series of post-dated cheques for each of those monthly instalments.

4.3 Partial Months

If the Term commences on a day other than the first day of a calendar month or if the Term expires or is terminated on a day other than the last day of a calendar month, then the Annual Base Rent and the Tenant's Percentage Share of Annual Operating Expenses and of Taxes for the first and last fractional months of the Term shall be prorated on the basis of a 365 day year.

4.4 Net Lease

This Lease shall be an absolutely net lease and the Annual Base Rent to be paid to the Landlord hereunder shall be net to the Landlord and shall yield to the Landlord the entire amount of such rent during the Term without the Landlord being liable to pay any costs or expenses and without the Landlord being obliged to fulfill any obligations of any kind or nature whatsoever relating to the Premises, whether or not referred to herein and whether or not of any kind now existing or within the contemplation of the parties hereto save as expressly set forth in this Lease.

The Tenant shall also pay any conveyance or registration tax which may be due by reason of execution of this Lease or any extension, amendment, supplement or renewal thereof.

4.5 No Waiver of Rent

The acceptance by the Landlord of a part payment of any sum required to be paid hereunder shall not constitute waiver or release of the right of the Landlord to payment in full of such sum.

5. ANNUAL BASE RENT - ADJUSTMENT

5.1 Rent Adjustment Provisions

The period from and including a Rent Adjustment Date to and including either the day preceding the next Rent Adjustment Date, or in the case of the last Rent Adjustment Date, to and including the last day of the Term, is herein called a "Rent Adjustment Period".

The Annual Base Rent for each Rent Adjustment Period shall be as agreed upon between the Landlord and the Tenant as being the fair rental value to the Tenant of the Premises at the commencement of the Rent Adjustment Period taking into account all Alterations then existing determined on the basis, inter alia, that such Alterations are required by the Tenant for the whole of the Rent Adjustment Period; provided, however, that if the Landlord requests an increase in Annual Base Rent and if the Landlord and the Tenant are unable to agree upon the Annual Base Rent for any such period at least ninety (90) days prior to the commencement thereof, the Annual Base Rent for such period shall be determined by arbitration (except if and so long as the Landlord and the Tenant agree to continue negotiations without arbitration) in accordance with the provisions hereof and otherwise in accordance with the arbitration legislation, if any, then in force in the jurisdiction in which the Building is situate but shall not in any event be less than the amount provided in subarticle 5.1(b). If the Landlord and the Tenant can agree on a single arbitrator, such arbitrator shall set the Annual Base Rent for such period. If the Landlord and the Tenant cannot agree on a single arbitrator at least sixty (60) days prior to the commencement of each Rent Adjustment Period, or by such later date as the Landlord or the Tenant may agree then either the Landlord or the Tenant may appoint an arbitrator and give notice in writing thereof to the other party, who shall within ten (10) days after receipt of such notice likewise appoint an arbitrator and so notify the first party, and, if such other party shall not appoint an arbitrator and so notify within said ten (10) day period, the arbitrator appointed by the first party shall act as a single arbitrator to determine the Annual Base Rent; provided however, that if the other party shall so appoint a second arbitrator and so notify, the two arbitrators so appointed shall meet and, within ten (10) days following the appointment of the second arbitrator, shall appoint a third arbitrator, and the three arbitrators so appointed shall constitute a board of arbitrators. If the two arbitrators so appointed cannot agree on a third arbitrator within ten (10) days, either party may apply to any judge of a court of competent jurisdiction, for the appointment of a third arbitrator. The single arbitrator or the board of arbitrators appointed as aforesaid shall have all the powers and duties prescribed for arbitrators by the provisions of the *Arbitration Act* or similar legislation in force from time to time in the province in which the Building is located. The single arbitrator or the board of arbitrators shall fix the Annual Base Rent based upon fair rental value to the Tenant at the commencement of the Rent Adjustment Period of the Premises with all Alterations then existing determined, inter alia, on the basis that such Alterations are required by the Tenant for the whole of that Rent Adjustment Period. The Annual Base Rent for the Rent Adjustment Period shall be either:

(a) the Annual Base Rent determined by arbitration; or

(b) the Annual Base Rent at the rate payable for the last month immediately preceding the period for which the rent is being determined,

whichever is the greater.

If the Landlord and the Tenant are unable to agree upon the Annual Base Rent and if such Annual Base Rent shall be referred to arbitration, the Tenant shall pay all costs of the arbitrator or arbitrators, including their fees and the reasonable legal fees of the Landlord.

If at the commencement of any Rent Adjustment Period the Annual Base Rent has not been agreed or determined the Tenant shall pay the new Annual Base Rent requested by the Landlord which amount will be retroactively adjusted when the Annual Base Rent is agreed or determined

6. OPERATING EXPENSES AND TAXES

6.1 Estimate of Operating Expenses

Prior to the commencement of each year during the Term or as soon thereafter as the Landlord can reasonably do so, the Landlord will furnish to the Tenant an estimate of the Operating Expenses for that year. The Tenant covenants and agrees to pay to the Landlord on the first day of each month of each year during the Term the amount calculated by the Landlord to be one-twelfth (1/12) of the Tenant's Percentage Share of such Operating Expenses for that year.

If the Landlord does not give the Tenant notice of the Tenant's monthly payment of the Tenant's Percentage Share of such Operating Expenses before the commencement of any year, the Tenant shall continue to make payments in an amount equal to the estimated monthly payments for the preceding

year and a retroactive adjustment will be made as may be appropriate, promptly following delivery of the Landlord's estimate for the then current year and the provisions of the second paragraph of subarticle 6.2 shall apply, mutatis mutandis. Until the Landlord gives the first notice to the Tenant of the Landlord's estimate of the Tenant's Percentage Share of Operating Expenses in the year in which the Term commences, the Tenant will pay to the Landlord as monthly instalments on account thereof the amount determined by applying the estimate stated in subarticle 1.1(q).

6.2 Adjustment of Operating Expenses

Statements of the Tenant's Percentage Share of Operating Expenses for each year shall be given to the Tenant within a reasonable period of time after the end of each year.

If the Tenant's Percentage Share of any Operating Expenses as shown on such statement is greater than the total amounts actually paid by the Tenant on account thereof, then within fifteen (15) days after delivery of such statement, the Tenant shall pay the difference to the Landlord. If the Tenant's Percentage Share of any Operating Expenses as shown on such statement is less than the total amounts actually paid by the Tenant on account thereof, then the Landlord will either, at its election, repay the excess to the Tenant or issue a credit note to the Tenant in which event, notwithstanding anything to the contrary herein contained, the Tenant shall receive credit for such amount against the next payment of Rent owing by the Tenant to the Landlord hereunder, provided it is not the end of the Term, in which case the Landlord will repay the excess directly to the Tenant.

If this Lease commences on a day other than the first or ends of any day other than the last day of a year, the Tenant's Percentage Share of Operating Expenses with respect to the year in which the Lease commences or ends shall be prorated on the basis of a 365 day year.

6.3 Operating Expenses

For the purposes hereof, "Operating Expenses" means all costs, charges and expenses incurred by the Landlord by reason of or in connection with the Landlord's ownership, management, operation, repair and maintenance of the Building including, without limitation:

(a) wages, salaries and other compensation benefits, as well as any adjustment thereto, for employees, independent contractors and agents of the Landlord;

(b) costs of service to and maintenance, inspection and repair of roofs, appurtenances, membranes, caulking, waterproofing, painting, landscaping, elevator, escalator, plumbing and electrical systems, automated control systems, security systems, mechanical equipment; the costs of purchasing or renting materials, supplies, mechanical equipment, tools and signs; the cost of janitorial, window cleaning, rubbish removal, snow removal and pest control services; and the cost of employee uniforms and the laundering and repair thereof;

(c) insurance premiums and other charges for insurance including, without limitation, reserves established by the Landlord for deductible amounts and losses in excess of insurance coverage, in each case, but without limitation, for all risk, earthquake, public liability, third party liability coverage, property damage (including plate glass, boiler, pressure vessel and mechanical equipment), workers' compensation insurance, loss of rental income and such other insurance coverage in such amounts as the Landlord and any mortgagee of the Lands, in their sole discretion, shall elect to maintain;

(d) the cost of electricity, water, gas, steam, sewer, telephone and other utility services not otherwise charged to tenants;

(e) Goods and Services Tax, Social Services Taxes, Use and Excise Taxes on goods and services purchased by the Landlord;

(f) license, permit and inspection fees;

(g) the cost of professional and consulting services;

(h) the costs, whether incurred before or during the Term, of any capital improvements, equipment or devices including cost of extended warranties, if any, installed or paid for by the Landlord in order

(i) to conform with any change in laws, rules or requirements of any governmental or quasi-governmental authority having jurisdiction or of the board of fire underwriters or similar insurance body, or

(ii) to effect a labour saving, energy saving or other economy, or

(iii) to improve security

amortised over the useful life of such capital improvement, equipment or device (as determined by the Landlord), plus interest on the unamortised balance at the Prime Rate or such higher rate as may have been paid by the Landlord from time to time on borrowed funds;

(i) the cost of exterior window draperies and coverings, carpeting and wallcoverings in the Common areas, and other furnishings in Common Areas, which, as a result of normal use, require periodic replacement. The full costs of such replacement will be included in the year they are incurred if less than 35% of such draperies, window coverings, carpeting or furnishings are replaced in that year; and if 35% or more of such draperies, window coverings, carpeting or furnishings are replaced in any year, whether before or during the Term, then there shall be included the cost thereof amortised over the useful life of such improvements (as determined by Landlord) plus interest on the unamortised balance at the Prime Rate or such higher rate as may have been paid by the Landlord from time to time on borrowed funds;

(j) depreciation or amortisation of the costs of materials, tools, supplies and equipment acquired either before or during the Term and which either require periodic replacement or which enable the Landlord to supply services which the Landlord might otherwise contract for with a third party;

(k) the cost of any work, the cost of which is chargeable to capital account, to repair, replace or renovate any part of the Building, whether before or during the Term, amortised over the useful life of such work (as determined by the Landlord), as well as interest on the unamortised balance at Prime Rate or such higher rate as may have been paid by the Landlord from time to time on borrowed funds;

(l) the costs (including, without limitation, legal fees, appraiser's fees and Landlord's administration and overhead costs) incurred in contesting Taxes or in respect of the Statement referred to in subarticle 6.6 or in legal proceedings taken in order to protect or preserve the general well-being of tenants of the Building and/or their use and enjoyment of the Building and/or to enforce covenants in the leases of the Building or any parts thereof and the Premises as they affect the general well-being of tenants in the Building;

(m) the charges and expenses of operating and maintaining the management office for the Building including, without limitation, the rental value thereof and a proportionate share of the Taxes and Operating Expenses attributed thereto in proportion to the rentable area thereof included in the calculation of the Building Rentable Area or, if such office is not in the Building, then the rental value thereof including amounts reasonably attributable thereto for real property taxes and the expenses of the building in which the same is situate;

(n) the costs and expenses of operating and maintaining each facility intended principally for use by tenants of the Building, including, without limitation, the costs of heating, air conditioning and cleaning. The Landlord may charge a fee for use of the facility which will be credited to Operating Expenses;

(o) in each year, a pro rate portion of any prepaid expenses as determined by the Landlord; and

(p) an amount equal to fifteen percent (15%) of the preceding costs under this subarticle 6.3 as management charges payable to the Landlord;

but excluding:

(q) any amount for depreciation, interest (except as otherwise provided above), capital retirement of debt or Landlord's costs of leasing parts of the Building, including the Premises whether by way of tenant inducements or otherwise; and

(r) any amounts (except services fees) charged to tenants in the Building, including the Tenant, under subarticle 6.7 hereof or corresponding articles in their leases;

and deducting:

(s) Operating Expenses which are recovered from insurance proceeds, to the extent that such recovery represents disbursements for costs previously included in Operating Expenses during the Term; and

(t) the costs of collecting parking revenue which are specifically parking management fees, wages, benefits, and the cost of accounting, tickets, cards, validation, supplies, uniforms, cashiers' equipment, parking control equipment and equipment maintenance.

6.4 Normalization

If in any year Operating Expenses are reduced because the Building is not fully occupied, Operating Expenses, both estimated and actual shall be adjusted, for the purpose of calculations under this Article, by adding amounts and items of expenses which would normally have been incurred if the Building had been fully occupied during the whole of such year and deducting any abnormal start-up costs, all as estimated by the Landlord.

6.5 Tenant's Percentage Share

Where used herein the phrase "Tenant's Percentage Share" means that fraction which has as its numerator the Premises Rentable Area and as its denominator the Building Rentable Area, except that the "Tenant's Percentage Share" with respect to any expense allocated by the Landlord, acting reasonably, to a part of the Building which includes the Premises or a part of the Premises shall be that fraction:

(a) which has as its denominator the rentable area of that part of the Building so designated by the Landlord; and

(b) which has as its numerator the rentable area of the Premises or the part thereof within the part of the Building so designated; and for the purposes of determining that fraction the rentable area of such part of the Building or of such part of the Premises shall be calculated by the Landlord in a manner consistent with the method then used to determine the Premises Rentable Area and the Building Rentable Area.

6.6 Statement of Operating Expenses and Taxes

The annual determination and statement of Operating Expenses and Taxes (the "Statement") shall be made by or verified by an accounting or auditing officer of the Landlord or an auditing company designated by the Landlord. Within three (3) months after receipt of the Statement the Tenant shall be entitled, upon five (5) days' prior written notice and during normal business hours at the Landlord's office or such other place as the Landlord shall designate, to inspect and examine the books and records of the Landlord relating to the determination of Operating Expenses and Taxes for the immediately preceding year. If, after inspection and examination of such books and records, the Tenant disputes the amounts of Operating Expenses or Taxes charged by the Landlord, the Tenant may, by written notice to the Landlord, request an independent audit of such books and records. The independent audit of the books and records shall be conducted by a Chartered Accountant or firm of Chartered Accountants (the "CA") appointed by the Landlord. The audit shall be limited to the determination as to whether the amount of Operating Expenses or Taxes billed to the Tenant was incorrect, and, if such amount is determined to be incorrect, the appropriate party shall pay to the other party the deficiency or overpayment resulting from such determination, as applicable. The result of the audit shall be binding upon the parties hereto. The fees and expenses paid by the Landlord to the CA shall be repaid to the Landlord by the Tenant unless the audit shows that the Landlord overstated Operating Expenses for the subject year by more than three percent (3%). The Tenant shall keep any information gained from such audit confidential and shall not disclose it to any other party. The exercise by the Tenant of its audit rights hereunder shall not relieve the Tenant of its obligation to pay when otherwise due hereunder all sums due hereunder, including, without limitation, the disputed Operating Expenses.

6.7 Special Tenant Expenses

The Tenant shall pay the Landlord upon demand the charges established by the Landlord from time to time for all supplementary services and utilities provided by the Landlord or its agents to the Tenant ("Special Tenant Expenses"). Such supplementary services and utilities shall include, without limitation, security, maintenance, repair, janitorial, cleaning and other services provided outside Ordinary Business Hours and/or in a manner not considered by the Landlord as standard. Where any other expense over and above normal Operating Expenses is incurred or paid by the Landlord specifically for the benefit of and at the request of the Tenant, the Tenant shall pay such expense. The Landlord may charge and the Tenant will pay a service fee for providing such services or for incurring such expense.

6.8 Estimate of Taxes

Prior to the commencement of each year during the Term or as soon thereafter as the Landlord can reasonably do so, the Landlord will furnish to the Tenant an estimate of the Taxes for that year. The Tenant covenants and agrees to pay to the Landlord at the option of the Landlord either:

(a) the amount calculated by the Landlord which is one-sixth (1/6) of the Tenant's Percentage Share of Taxes for that year on the first day of each month of the first six (6) months of each calendar year during the Term; or

(b) the amount estimated by the Landlord to be the Tenant's Percentage Share of any Taxes or instalment of Taxes payable by the Landlord in which event such amount shall be paid by the Tenant to the Landlord seven (7) days in advance of the due date for payment by the Landlord of such Taxes or instalment of Taxes.

If the Landlord does not give the Tenant notice of the Tenant's monthly payment of the Tenant's Percentage Share of such Taxes before the commencement of any year, the Tenant shall continue to make payments in an amount equal to the estimated monthly payments for the preceding year and a retroactive adjustment will be made promptly following delivery of the Landlord's estimate for the then current year and the provisions of the second paragraph of subarticle 6.9 shall apply, mutatis mutandis. Until the Landlord gives the first notice to the Tenant of the Landlord's estimate of the Tenant's Percentage Share of Taxes in the year in which the Term commences, the Tenant will pay to the Landlord as monthly instalments on account thereof the amount determined by applying the estimate stated in subarticle 1.1(r).

6.9 Adjustment of Taxes

Statements of the Tenant's Percentage Share of Taxes for each year shall be given to the Tenant within a reasonable period of time after the end of each year.

If the Tenant's Percentage Share of any Taxes as shown on such statement is greater than the total amounts actually paid by the Tenant on account thereof, then within fifteen (15) days after delivery of such statement, the Tenant shall pay the difference to the Landlord. If the Tenant's Percentage Share of any Taxes as shown on such statement is less than the total amounts actually paid by the Tenant on account thereof, then the Landlord will either, at its election, repay the excess to the Tenant or issue a credit notice to the Tenant in which event, notwithstanding anything to the contrary herein contained, the Tenant shall receive credit for such amount against the next payment of Rent owing by the Tenant to the Landlord hereunder, provided it is not the end of the Term, in which case, the Landlord will repay the excess directly to the Tenant.

If this Lease commences on a day other than the first day or ends of any day other than the last day of a year, the Tenant's Percentage Share of Taxes with respect to the year in which the Lease commences or ends shall be prorated on the basis of a 365 day year. Taxes for any lease commencing after June 30 are due in their entirety fifteen (15) days after the Commencement Date.

6.10 Taxes

In this Lease "Taxes" means all taxes, assessments and charges levied upon or with respect to the Building or any part thereof or any personal property of the Landlord used therefor, or upon the Landlord on account thereof, including, without limitation, all real property taxes and general and special assessments, charges, fees, levies or assessments for transit, housing, schools, police, fire or other governmental services or for purported benefits to the Building; local improvement taxes service payments in lieu of taxes; and capital taxes and special taxes, which may now or hereafter be levied or assessed against the Landlord by the Government of Canada, the Provincial Government, or any political subdivision, public corporation, district or other political or public entity, and any other tax, fee or other excise, however described, that may be levied or assessed as a substitute for, or as an addition to (in whole or in part) any other property taxes or local improvement tax, whether or not now customary or in the contemplation of the parties on the date of this Lease; but excluding Tenant's Taxes, Goods and Services Tax and like amounts with respect to other tenants in the Building.

6.11 Tax Appeals

The Landlord may contest any Taxes and appeal any assessments with respect thereto; withdraw any such contest or appeal; and agree with the taxing authorities on any settlement or compromise with respect to Taxes. The Tenant will co-operate with the Landlord in respect of any such contest or appeal and will provide the Landlord with all relevant information, documents and consents required by the Landlord in connection with any such contest or appeal. The Tenant will not contest any Taxes or appeal any assessments related thereto without the Landlord's prior written consent and will then do so only in accordance with such conditions as the Landlord may impose.

6.12 Tenant's Taxes

The Tenant shall promptly pay as they become due Tenant's Taxes. In this Lease "Tenant's Taxes" means all taxes, license and permit fees, rates, duties and assessments and penalties and interest thereon or relating thereto imposed or levied by lawful authority during or after the Term and relating to or in respect of the business of the Tenant or relating to or in respect of its personal property or business and trade fixtures, machinery and equipment, cabinet work, furniture and movable partitions owned or installed by or for the Tenant or relating to or in respect of Alterations whether any such taxes are by law payable by the Tenant or by the Landlord and whether such taxes are included by the taxing authority in Taxes, licenses, rates, duties and assessments imposed or levied on or with respect to the Premises or the Building. The Tenant further covenants and agrees that upon written request of the Landlord, the Tenant will promptly deliver to it for inspection receipts for payment of all of the Tenant's Taxes which were due and payable up to one (1) month prior to such request, and in any event will furnish to the Landlord before the 21st day of January in each year if requested by the Landlord, evidence satisfactory to the Landlord of payment of all Tenant's Taxes for the preceding year.

6.13 Reimburse Landlord

If the Landlord is required by lawful authority or considers it desirable to pay the Tenant's Taxes which the Tenant fails or neglects to pay the Tenant shall pay the amount thereof to the Landlord forthwith after written request therefor.

6.14 Goods and Services Tax

"Goods and Services Tax" (GST) shall mean the tax proposed to be levied and contained in Part IX to the Excise Tax Act (Canada) and in consequential amendments to other federal statutes, as amended from time to time and any other taxes, fees, levies, charges, assessments, duties and excises (whether characterized as sales tax, purchase tax, value-added tax, goods and services tax or any other form) which are imposed on the Landlord or which the Landlord is liable to pay, and which are levied, rated or assessed by any governmental authority whatsoever on the act of entering into this Lease or otherwise on account of this Lease, or on the use of occupancy of the Premises or any portion thereof, or on the Rent or any portion thereof, or in connection with the business of renting the Premises or any portion thereof, but excluding Taxes and income tax under Part 1 of the Income Tax Act of Canada as at the date of this Lease;

7. SECURITY DEPOSIT

The Tenant has deposited with the Landlord the Security Deposit specified in subarticle 1.1(m). The Security Deposit shall be held by the Landlord as security for the faithful performance by the Tenant of all of the provisions of this Lease to be performed or observed by the Tenant. If the Tenant fails to pay Rent or otherwise defaults with respect to any provision of this Lease, the Landlord may use, apply or retain all or any portion of the Security Deposit for the payment of any Rent in default, or for the payment of any other expense which the Landlord may incur by reason of the Tenant's default, or to compensate the Landlord for any loss or damage which the Landlord may suffer thereby. If the Landlord so uses or applies all or any portion of the Security Deposit, the Tenant shall within ten (10) days after demand therefor deposit cash with the Landlord in an amount sufficient to restore the Security Deposit to the full amount thereof. The Landlord shall not be required to keep the Security Deposit separate from its general accounts. If the Tenant performs all of the Tenant's obligations hereunder, the Security Deposit, or so much thereof as has not theretofore been applied by the Landlord, shall be returned, without payment of interest or other increment for its use, to the Tenant at the expiration of the Term, and after the Tenant has vacated the Premises. No trust relationship is created herein between the Landlord and the Tenant with respect to the Security Deposit.

Notwithstanding anything to the contrary, the Tenant provides herein a deposit in the amount of $24,770.66 to the Landlord as the Security Deposit (the "Security Deposit"). $12,281.77 of the Security Deposit will be applied to first month's Rent with the balance in the amount of $12,488.88 to be held without interest until the end of Term for the fulfilment by the Tenant of all its obligations hereunder.

8. USE

8.1 General

The Premises shall be used only for the purposes specified in subarticle 1.1(n). Notwithstanding anything to the contrary contained in this Lease; the Tenant shall not::

(a) permit the use by other tenants in the Building of equipment placed or installed in the Premises or placed or installed elsewhere in the Building on behalf of the Tenant, and the Tenant shall not use or permit the use of such equipment to provide technological, computer, telecommunication or other services to tenants in the Building except in each case with the prior written consent of the Landlord and on such terms and conditions and for such period as the Landlord may specify in each such consent; or

(b) use or permit the use of the Premises or any part thereof as a personnel office or labour hiring hall for business conducted outside the Premises.

8.2 No Nuisance or Waste

The Tenant shall not do or permit anything to be done in or about the Premises or the Building which will in any way obstruct or interfere with the rights of other tenants or occupants of the Building or any adjacent property or injure or annoy them; and shall not use or allow the Premises to be used for any improper, immoral or objectionable purpose; not shall the Tenant cause, maintain or permit any nuisance in, on, or about the Premises or keep therein any dangerous substance; nor shall the Tenant use an apparatus, machinery or device in or about the Premises which shall cause any substantial noise or vibration; nor shall the Tenant overload the floor of the Premises. If any of the Tenant's office machines and equipment should disturb any other tenant in the Building, then the Tenant shall provide adequate insulation, or take such other action as may be necessary to eliminate the disturbance. The Tenant shall not commit or suffer the commission of waste in, on, or about the Premises.

8.3 No Illegal Use

The Tenant shall not use the Premises or permit anything to be done in or about the Premises which will in any way conflict with any law, statute, ordinance or governmental rule or regulation now in force or which may hereafter be enacted or promulgated. The Tenant shall not do or permit anything to be done in or about the Premises or bring or keep anything therein which will in any way increase the rate of fire insurance upon the Building or any of its contents, and the Tenant shall, at its sole cost and expense, promptly comply with all laws, statutes, ordinances, and governmental rules, regulations and requirements now in force or which may hereafter be in force, and with the requirements of the Landlord's insurers and any board of fire underwriters or other similar body now or hereafter constituted relating to or affecting the condition, use, or occupancy of the Premises, excluding structural changes not related to or affected by the Tenant's alterations or improvements. The judgment of any court of competent jurisdiction or the admission of the Tenant in an action against the Tenant, whether the Landlord be a party thereto or not, that Tenant has so violated any law, statute, ordinance, or governmental rule, regulation or requirement, shall be conclusive of such violation as between Landlord and Tenant.

8.4 Alterations to the Building

If changes or alterations are made by the Landlord to any portion of the Building (including without limitation the Common Areas) other than the Premises, and which do not materially impair the Premises, the Landlord shall not thereby be subject to any liability nor shall the Tenant be entitled to any compensation or any diminution or abatement of Rent; and such changes or alterations shall not be deemed to be a constructive or actual eviction or a breach of the Landlord's covenant of quiet enjoyment.

8.5 Tidiness

The Tenant shall keep the Premises in good and tidy condition at all times consistent with the condition of a first class office building; and shall provide proper and sufficient receptacles for waste; and shall leave the Premises each day in a condition which reasonably facilitates the performance of cleaning and janitorial services as herein provided.

8.6 Change of Name

The Tenant shall immediately notify the Landlord of any change of the name of the Tenant and pay all expenses incurred by the Landlord for changes of any Building directory and other consequential changes.

8.7 Rules and Regulations

The Tenant shall observe and shall cause its employees, servants, invitees, licensees, agents and all others over whom the Tenant exercises control to observe faithfully and comply strictly with the rules and regulations attached hereto as Exhibit "B" and made part of this Lease and such other and further reasonable rules and regulations and any amendments thereto as the Landlord may from time to time adopt for the Building as a whole. Written notice of any additional rules and regulations shall be given to the Tenant. Such rules and regulations may differentiate between different types of businesses in the Building. Nothing in this Lease contained shall be construed to impose upon the Landlord any duty or obligation to enforce the rules and regulations against any other tenant of the Building or to enforce the terms, covenants or conditions in any other lease and the Landlord shall not be liable to the Tenant for violation of the same by the other tenant, its servants, employees, agents, visitors or licensees.

The rules and regulations in Schedule "B" hereto have been adopted for the purpose of ensuring order and safety in the Building and to maintain the rights of tenants and the Landlord. The Landlord reserves the right to make such other reasonable rules and regulations as in its judgment from time to time be needed and to modify, supplement and rescind any of these rules and regulations. The Landlord may waive any one or more of these rules and regulations for the benefit of any particular tenant or tenants, but no such waiver by the Landlord shall be construed as a waiver of such rules and regulations in favour of any other tenant or tenants, nor prevent the Landlord from thereafter enforcing any such rules and regulations against any or all of the tenants of the Building. The Landlord shall not be responsible to the Tenant or to any other person for the non-observance or violation of these rules and regulations by any other tenant or other person. The Tenant agrees to abide by all such rules and regulations. The Tenant shall be liable for injury or damage caused by the infraction of any of these rules by it, its employees, agents or invitees, and the Landlord may repair such damage, charging the cost of the same to such tenant, which amount shall be added to Rent due for the ensuing month. These rules and regulations are in addition to, and shall not be construed to in any way modify or amend, in whole or in part, the terms, covenants, agreements and conditions of any lease of premises in the Building.

9. SERVICES AND UTILITIES

9.1 General

So long as the Tenant is not in default in the performance of its obligations under this Lease:

(a) the Landlord shall operate or cause to be operated in season the heating, ventilating and air-conditioning systems of the Building ("HVAC Systems") during Ordinary Business Hours (as determined by the Rules and Regulations) by providing air or water or both at such temperatures and in such quantities as the Landlord determines as being reasonably required for the comfortable occupancy of the Building. If the Premises are situate on a floor of the Building which is at or below ground level, the Tenant agrees to install at its own expense such supplementary equipment as may be necessary to make use of such water or air or both and to maintain and operate such equipment so as to maintain a reasonable temperature in the Premises.

Any heating, ventilating and air-conditioning ("HVAC") provided by the Landlord to the Tenant other than during Ordinary Business Hours shall be furnished only upon the written request of the Tenant made in accordance with the Rules and Regulations and shall be provided at the Tenant's sold cost and expense which shall be charged by the Landlord and paid by the Tenant at an amount equal to the Landlord's cost of supplying HVAC to the Premises as estimated by the Landlord plus 15%. Should other tenants in the same HVAC zone of the Building also request HVAC during such period then the Tenant's share of the charge for such HVAC shall be apportioned pro rata by the Landlord in relation to rentable area and time of use. The Tenant shall also be responsible for and shall pay to the Landlord any additional costs estimated by the Landlord (including without limitation the cost of installation of additional HVAC equipment or of altering the HVAC System) incurred by the Landlord because of the failure of the HVAC System to perform its function due to Alterations or due to the use of any heat generating machinery or equipment or due to the occupancy of the Premises or the part thereof on any floor of the Building exceeding one (1) person per one hundred twenty-five (125) square feet of the Premises Rentable Area or of the rentable area of the part of the Premises on that floor or due to the failure of the Tenant to keep all HVAC vents within the Premises free of obstruction;

(b) the Landlord shall provide warm and cold water in the washrooms on each floor; and shall at its option from time to time either provide electric current to the Premises or make arrangements with public utilities and/or public agencies to furnish electric current to the Premises in amounts sufficient for normal building standard fluorescent lighting and for normal use of typewriters and other office machines of similar low electrical consumption. The Landlord cannot guarantee that there will not be voltage fluctuations and the Tenant is responsible for the installation of clear line circuits, surge protectors and any other devices necessary to protect or operate its equipment. The Tenant shall not install any piece of equipment (including without limitation any electronic data processing equipment, independent air-conditioning units or special communications equipment) which (singly) consumes more than one and a half (1-1/2) kilowatts of electricity per hour at rated capacity or which requires a voltage greater than 120 volts per single phase (such equipment being herein called "High Consumption Equipment") without in each case the Landlord's prior written consent. The Landlord may provide electric current for High Consumption Equipment, installed with such consent, up to the rated capacity of such equipment or may make the aforesaid arrangements to have such electric current provided. The Tenant shall advise the Landlord prior to the execution of this Lease and thereafter from time to time within five (5) days after receipt of the written request of the Landlord, of the nature and quantity of all lights, equipment and machines using electricity in the Premises and shall permit the Landlord or its authorized agent to make periodic inspections of all equipment using electricity within the Premises. Should the Landlord supply electric current or any other utility used or consumed on the Premises, the Tenant shall pay the Landlord for the same at rates determined by the Landlord not in excess of the public utility rates for the supply of the same electric current or other utility in the same quantity and with the same load limits as if supplied only to the Tenant at the Premises notwithstanding that electric current or such other utility may be purchased by the Landlord on some other basis, whether in bulk or otherwise.

The Landlord shall be entitled to estimate the consumption of electric current or other utility on the Premises.

The Landlord shall also have the right to install one or more meters in the Premises to measure the amount of electric current or other utility consumed on the Premises. The cost of such meters and of special conduits, wiring and panels needed in connection therewith and the cost of installation, maintenance and repair thereof and of periodic readings thereof shall be paid by the Tenant.

The Tenant covenants and agrees that at all times its use of electric current and other utilities in the Premises will not exceed the capacity of the electrical wiring or other ducts or facilities by which electricity or any other utility is provided to the Premises.

(c) the Landlord shall operate, maintain, clean, light, heat, ventilate and air-condition the Common Areas used for access to the Premises and other leasable parts of the Building and provide such security as may be reasonably necessary. The Landlord shall not be liable to the Tenant for losses due to theft or burglary, or for damages done by unauthorized persons in the Building. The Landlord shall provide elevator service in the Building on a twenty-four (24) hours per day, seven (7) days per week basis but use thereof may be limited to authorized access and may be at reduced frequency after Ordinary Business Hours.

(d) the Landlord shall provide janitorial service following Ordinary Business Hours on each weekday, exclusive of holidays, subject to access being granted to the person or persons employed or retained by the Landlord to perform such work. The Landlord shall not be required to provide janitorial services for portions of the Premises used for preparing or consuming food or beverages, or for washrooms (other than standard washrooms) but may do so at its option and in that event any special cost incurred by the Landlord shall be paid by the Tenant under subarticle 6.7; and

(e) the Landlord shall have the exclusive right to replace lamps, tubes and ballasts in the lighting system in the Premises, on either an individual or a group basis. If the Landlord waives that right in whole or in part with respect to special light fixtures or lamps or tubes, such special light fixtures, bulbs or tubes shall be maintained by the Tenant at the Tenant's expense.

"Common Areas" means those areas, facilities, utilities, improvements, equipment and installations in or adjacent to the Building which serve or are for the benefit of tenants of any part of the Building and which are not intended from time to time by the Landlord to be leased, and which are provided or designated (and which may be changed from time to time) by the Landlord for the benefit or use of such tenants, their employees, customers and invitees, in common with others entitled to the use or benefit of such areas, facilities, utilities, improvements, equipment and installations. Without limiting the generality of the foregoing, Common Areas includes truck docks, receiving areas and loading docks; service corridors; elevators, escalators and stairways; electrical, telephone, meter, valve, mechanical, storage and janitor rooms; music, fire prevention, security and communication systems and other Building Systems; general signs; columns, structural elements and bearing walls; sidewalks, ramps, laneways and other means of ingress to and egress from the Building or any part thereof; pipes, electrical, plumbing, drainage, refuse removal and mechanical installations and services; and structures housing any of the foregoing.

9.2 Interruption of Access, Use or Services

The Landlord shall not be liable for any interruption of access to the Premises or of the beneficial use of the Premises or of any services or utilities when such interruption is caused by natural occurrences, riots, civil disturbances, insurrection, war, court orders, public enemy, accidents, breakage, repairs, electrical voltage fluctuations, strikes, lockouts, other labour disputes, the making of inspections, repairs, alterations, renovations or improvements to the Premises or the Building, the inability to obtain an adequate supply of fuel, gas, steam, water, electricity, labour or other supplies or if required by insurers or if caused by any other condition beyond the Landlord's reasonable control, or by delays in the performance of any work for which the Landlord is responsible under this Lease, and the Tenant shall not be entitled to any damages resulting from such failure, nor shall failure relieve the Tenant from its obligation to pay all sums due hereunder or constitute or be construed as a constructive or other eviction of the Tenant. If any governmental entity promulgates or revises any statute or ordinance or building, fire or other code, or imposes mandatory or voluntary controls or guidelines on the Landlord or the Building or any part thereof, relating to the use or conservation of energy, water, gas, steam, light or electricity or the provision of any other utility or service provided with respect to the Premises, or if the Landlord is required or elects to make alterations to the Building in order to comply therewith, the Landlord may do so; and neither such compliance nor the making of such alterations shall in any event entitle the Tenant to any damages, relieve the Tenant of the obligation to pay any of the sums due hereunder, or constitute or be construed as a constructive or other eviction of the Tenant; and the Landlord shall not be in breach of its covenant for quiet enjoyment or liable for any loss, costs or damages, whether direct or indirect, incurred by the Tenant due to any of the foregoing, but the Landlord shall make reasonable efforts to restore the services, utilities or systems so stopped, interrupted or reduced. The Landlord shall not be liable for damages, direct, indirect or consequential or for damages for personal discomfort, illness or inconvenience of the Tenant or the Tenant's servants, employees, invitees or other persons by reason of the failure of the Building Systems or any of them including without limitation the elevators and HVAC Systems or by reason of reasonable delays in the performance of the obligations of the Landlord hereunder whether or not such equipment failure or delays are caused by the deliberate act or omission or the negligence of the Landlord, its servants, agents or employees.

10. REPAIRS AND ALTERATIONS

10.1 Alterations

In this Lease "Alterations" means any construction in, alteration of, replacement in, installation in, removal from or decoration of the Premises and any fixtures, including tenant fixtures, in the Building including without limitation the Premises and the Common Areas, whether made by or on behalf of the Tenant during the Term or made by or on behalf of the Tenant or any previous tenant of the Premises or any part thereof prior to the Term and without limiting the generality of the foregoing, includes all improvements existing at the Commencement Date or at any time thereafter built by anyone in the Premises, including, without limitation, all walls and partitions which are not load-bearing, the interior decorated or finished surfaces of all perimeter and load-bearing walls and floor slabs, all non-standard ceilings and ceiling light fixtures, all interior windows, all entrance doors, all mechanical and electrical conduits, wiring, fixtures and equipment, all floor tile, carpeting and wall covering and all other fixtures of all kinds but excluding Building Systems.

The Tenant shall not make or cause to be made any Alterations without in each case the prior written consent of the Landlord which, in the case of Alterations in, on or to the Premises, shall not be unreasonably withheld. Without limiting the generality of the foregoing, the Tenant agrees that the Tenant will not alter or mark the exterior walls or doors of the Premises or the finishing of the lobby on any multi-tenant floor of the Building upon which the Premises or any part thereof are situate.

When applying for any such consent, the Tenant shall submit to the Landlord details of the proposed work including drawings and specifications prepared by qualified architects or engineers conforming to good engineering practice, and in compliance with any tenant construction guidelines from time to time established for the Building by the Landlord. Subsequent to obtaining the Landlord's consent and prior to commencement of any Alterations, the Tenant shall deliver to the Landlord the building permit covering the Alterations and a copy of the executed construction contract.

The Tenant shall pay to the Landlord upon demand a reasonable fee to compensate the Landlord for the cost of review and approval of the plans and specifications including any fees charged by an architect or engineer employed by the Landlord for such review and for additional administrative costs incurred in monitoring the Alterations.

If the Landlord consents to any Alteration, such Alteration shall be made by the Tenant at the Tenant's sole cost and expense and any other work which the Landlord considers necessary, acting reasonably, as a result thereof shall be done either by the Landlord or by the Tenant, as the Landlord may determine, but in any event at the Tenant's sole cost and expense.

Any contractor or person selected by the Tenant to make any Alterations must first be approved in writing by the Landlord. The Landlord reserves the right, either by itself or by its contractors, to make any Alterations affecting the Building Systems which is required by reason of any Alterations requested by the Tenant. The Tenant shall provide, at its expense, such completion, performance and/or payment bonds as the Landlord considers necessary with respect to Alterations. The Tenant shall also require its contractor to maintain insurance in amounts and in such form as the Landlord may require.

Any and all Alterations, maintenance and repair undertaken by the Tenant in connection with the Premises shall be completed in accordance with plans and specifications approved by the Landlord, shall be carried out in a good, workmanlike and prompt manner and at such times and in such manner as the Landlord may approve and in accordance with the Rules and Regulations and the Tenant shall comply with all applicable statutes, laws, ordinances, regulations, rules, orders and requirements of authorities having jurisdiction thereof, and shall be subject to supervision by the Landlord or its employees, agents or contractors.

Without the Landlord's prior written consent the Tenant shall not use any portion of the Common Areas in connection with the making of any Alterations except for access and deliveries. All Alterations and all such access and deliveries shall be in accordance with any guidelines established therefor by the Landlord from time to time.

The Landlord may elect to construct the Alterations desired by the Tenant. If the Landlord so elects, the Tenant shall reimburse the Landlord for any and all reasonable costs therefor (including, without limitation, the costs of design, labour, materials, equipment and the Landlord's cost of review, approval and supervision of the construction of the Alterations by the Landlord or by consultants on behalf of the Landlord) within ten (10) days after receipt of the Landlord's invoice. Failure of the Tenant to pay the invoiced costs within such ten (10) day period shall constitute a default under the terms of this Lease in like manner to failure to pay Rent when due. In the event of any such failure of the Tenant to pay such costs when due, the Landlord shall thereby be entitled without cost, obligation or liability of any kind or in any amount whatsoever, to discontinue the construction of any Alterations.

If the Alterations which the Tenant causes to be constructed result in the Landlord being required to make any changes in or to other portions of the Building in order to comply with any applicable

statutes, laws, ordinances, regulations, rules, orders or requirements, including without limitation, ordinances intended to provide full access to handicapped persons, the Tenant shall reimburse the Landlord upon demand for all costs and expenses incurred by the Landlord in making such changes.

The Tenant shall not cause or permit any Alterations to be made under the terms of a conditional sale or similar contract; and shall not permit any notice of a conditional sale or like contract to be filed affecting the title to the Building. At the end of the Term the Tenant will, except as the Landlord may otherwise agree, restore the Premises and the light fixtures and other facilities and equipment therein to the Building standard if and to the extent that the Tenant has substituted alternate fixtures and equipment prior to the commencement of the Term or during the Term.

If any Alteration consists of ceilings or floor coverings which restrict access to utility lines or Building Systems, the Tenant specifically acknowledges and agrees that the Landlord shall be entitled to cut through the same whenever and so often as the Landlord or any persons authorized by the Landlord require access through such ceilings or floor coverings to those utility lines or Building Systems; and the Tenant shall be solely responsible for the restoration and shall promptly restore such ceilings and floor coverings.

10.2 Notice of Alterations

The Tenant shall give the Landlord at least fifteen (15) days' prior written notice of commencement of any Alteration in order to enable the Landlord to post and record notices for the purpose of preventing any lien attaching to the Premises, the Building or the Lands or any part thereof.

10.3 Labour Relations

If, in the opinion of the Landlord, the making of any Alteration interferes with or adversely affects labour relations in or affecting the Building or the Landlord or any occupant of the Building, all such work shall be halted immediately by the Tenant until such time as Alterations can proceed without any such interference.

10.4 Indemnity

The Tenant shall indemnify the Landlord against any and all loss, cost, damage, injury and expense arising out of or in any way related to claims for work done or labour performed, or materials or supplies furnished, to or at the request of the Tenant in connection with performance of any work done for the account of the Tenant in the Premises or the Common Areas or both, whether or not the Tenant obtained the Landlord's permission to have such work done, labour performed, or materials or supplies furnished.

10.5 No Liens

The Tenant shall not suffer or permit any builder's lien to be filed against or attach to the Lands or the Building or any part thereof or the interest of the Landlord therein by reason of work, labour, services, or material supplied or claimed to have been supplied to or for the Tenant. If any such lien shall at any time arise or be claimed, the Tenant shall cause the same to be discharged and to be removed from the title or titles thereto in all offices of public record within twenty (20) days after the date the Tenant first has knowledge thereof and upon failure to do so by the Tenant, then the Landlord, in addition to any right or remedy, may, at any time, and without being required to give any notice to the Tenant, discharge the same by paying the amount claimed to be due or by procuring a discharge of such liens by deposit in Court or in such manner as may be permitted by law; but the Landlord shall not be obliged to do so; and in any such event the Landlord shall be entitled, if it so elects, to expedite the prosecution of any action for the enforcement of such lien by the lien claimant and to pay the amount of the judgment, if any, in favour of the lien claimant with interest, costs and expenses. In any such event the Tenant shall forthwith pay to and reimburse the Landlord for all monies expended, and all costs and expenses incurred by the Landlord.

The Landlord may post any notice or notices upon the Premises which the Landlord may consider necessary or desirable for the prevention of any liens or claims of lien with respect to any work, labour, services or material performed or supplied or to be performed or supplied in or about the Premises.

10.6 Accidents Etc.

The Tenant shall immediately notify the Landlord of any accident, defect, deficiency or dangerous condition in any part of the Premises or the Building, which comes to the attention of the Tenant, its employees or contractors notwithstanding that the Landlord may have no obligation in respect thereof; and the Tenant shall immediately remove, make good or repair any such defect, damage, deficiency or dangerous condition or the cause of any such accident within the Premises or relating to any Alterations.

10.7 Tenant Repairs

No representations, except as contained herein, have been made to the Tenant respecting the condition of the Premises. The Tenant shall take good care of the Premises and shall make all repairs as

and when the Landlord deems necessary, acting reasonably, in order to preserve the Premises in good order and in good and tenantable condition. In addition, the Tenant shall reimburse the Landlord, upon demand, for the cost of any and all structural repairs or replacements necessitated or occasioned by the acts, omissions or gross negligence of the Tenant or any person claiming through or under the Tenant, or any of their servants, employees, contractors, agents, visitors or licensees, or by the use or occupancy of the Premises by the Tenant or any such person. The Landlord shall not be liable for, and there shall be no abatement of Rent or other amounts payable hereunder with respect to, any injury to or interference with the Tenant's business arising from any repairs, maintenance, alteration or improvement in or to any portion of the Premises, the Common Areas or the Building or in or to the fixtures, appurtenances or equipment therein. The Tenant hereby waives all right to make repairs at the Landlord's expense and instead, all improvements, repairs and/or maintenance expenses incurred on the Premises shall be at the expense of the Tenant, and shall be considered as part of the consideration for leasing the Premises. The Tenant shall save harmless and indemnify the Landlord from and against all loss, costs, expenses, damages, claims, causes of action and actions of whatsoever nature resulting from any damage or injury done to the Building or any part thereof by the Tenant or any person who may be in or upon the Building with the Tenant's consent or at the Tenant's invitation. On the expiration or earlier termination of this Lease the Tenant shall surrender the Premises to the Landlord which, after removal of any Alterations required in accordance with the terms hereof (but only those so required) shall be in as good condition and in as good a state of repair as at the commencement of the Term, reasonable wear and tear excepted.

10.8 Alterations are Landlord's Property

Provided further that any and all Alterations in, to or upon the Premises, whether placed there by the Tenant or the Landlord or a previous occupant of the Premises, shall, immediately upon such placement, become and shall thereafter remain the property of the Landlord without compensation to the Tenant. Notwithstanding anything herein contained, the Landlord shall be under no obligation to repair, maintain, replace or insure such Alterations or anything in the nature of a leasehold improvement made or installed by or on behalf of the Tenant or a previous occupant of the Premises.

10.9 Trade Fixtures Etc.

The Tenant covenants that it will not sell, dispose of or remove from the Premises any of the trade fixtures or other goods or chattels of the Tenant required for the conduct of the Tenant's business in the Premises without the consent of the Landlord, unless the Tenant is substituting new trade fixtures and such goods or chattels of equal value or is bona fide disposing of individual items which have become excess for the Tenant's purposes in the normal course of its business. The Tenant further covenants that it will at all times have and retain full legal and beneficial ownership of such trade fixtures and such goods and chattels and will not permit them to be or become subject to any lien, mortgage, charge, encumbrance or title retention agreements except such are bona fide incurred for the purpose of financing the purchase thereof.

Except to the extent expressly agreed by the Landlord in writing, no trade fixtures, furniture or equipment shall be removed by the Tenant from the Premises either during or at the expiration or sooner termination of the Term except that (a) the Tenant if not in default hereunder, may at the end of the Term remove such of its trade fixtures, furniture and equipment; and (b) the Tenant shall at the end of the Term remove such of its trade fixtures, furniture and equipment as the Landlord shall require to be removed. The Tenant shall, in the case of every removal either during or at the end of the Term, make good any damage caused to the Premises and the Building by the installation and removal.

10.10 Landlord's Alterations

The Landlord hereby reserves the right at any time and from time to time to make changes to, additions to, and re-arrangements of the Building and to remove parts of the Building including without limitation, all improvements at any time therein, and all entrances thereto and exits therefrom, and to grant, modify and terminate easements or other rights pertaining to the use and maintenance of all or parts of the Building. The Landlord may alter the boundaries of the Premises to the extent considered necessary by the Landlord, acting reasonably, to accommodate changes to the Building.

10.11 Landlord's Repairs

Subject to the provisions of articles 16.1, 16.2 and 16.3 and, in the event of damage to the Building, only to the extent that insurance proceeds are available to the Landlord for the repair thereof, the Landlord covenants with the Tenant to keep or cause to be kept in good repair, order and condition, consistent with the standard of a prudent owner, the foundations, structural portions of the sub-floors, structural portions of the roofs, structural portions of the bearing walls, structural columns, and structural beams of the Building.

11. ACCESS TO PREMISES BY THE LANDLORD

The Landlord may enter the Premises upon providing the Tenant with reasonable notice, except in case of real or suspected emergency no notice is needed:

(a) to inspect the same or to inspect Building Systems, elevator systems or HVAC systems;

(b) to exhibit the Premises to prospective purchasers, lenders or tenants;

(c) to determine whether the Tenant is complying with all of its obligations hereunder;

(d) to supply janitorial service and any other service to be provided by the Landlord to the Tenant hereunder or to any other tenant of the Building, and no notice is required for such services;

(e) to post notices of non-responsibility;

(f) to make repairs, additions or alterations required of the Landlord under the terms of this or any other lease or considered advisable by the Landlord to make repairs or additions or alterations to any other portion of the Building;

(g) to determine the electric light, power and utility consumption by the Tenant including installation of measuring devices to the Tenant's equipment; and

(h) to install meters;

provided, however, that the exercise of such rights shall be done promptly and so as to minimize interference to the Tenant; and the Tenant hereby waives any claim for damages for any injury or inconvenience to or interference with the Tenant's business, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby. The Landlord shall at all times have and may retain a key with which to unlock all of the doors in, on or about the Premises (excluding the Tenant's vaults, safes and similar areas agreed upon in writing by the Tenant and the Landlord). The Landlord shall have the right to use reasonable means which the Landlord may deem proper to open such doors in an emergency in order to obtain entry to the Premises, and no entry upon the Premises by the Landlord under this Article11 by any of such reasonable means shall under any circumstances be construed or deemed to be a re-entry by the Landlord or to be a forcible or unlawful entry into the Premises or an eviction, actual or constructive, of the Tenant from the Premises, or any portion thereof.

12. ASSIGNMENT AND SUBLETTING

12.1 Requirement for Consent

The Tenant shall not assign this Lease or sublet or part with or share possession of all or part of the Premises or confer on any person or corporation any right enjoyed by the Tenant hereunder or permit any subtenant to do so and the Tenant shall not assign this Lease or permit any subtenants to assign its sublease without the prior written consent of the Landlord which shall not be unreasonably withheld; but the Landlord may withhold its consent if the proposed transaction is of the nature described in subarticle 12.2(B) or (C) or if any consent required under any mortgage of the Lands or the Building or this Lease is not first obtained. No assignment of this Lease shall be valid or effective prior to the giving of the Landlord's written consent thereto.

12.2 Landlord's Option

Notwithstanding and without prejudice to any other provision herein, in the event that the Tenant desires to assign, sublet or part with or share possession of all or any part of the Premises, or to confer on any person or corporation any right enjoyed by the Tenant hereunder in any other manner or to transfer any estate or interest hereunder, then and so often as such event shall occur, the Tenant shall give prior written notice to the Landlord of such desire, specifying therein the proposed assignee, transferee, sublessee or occupier and shall provide to the Landlord in writing such information as to the nature of the business of the proposed assignee, transferee, sublessee or occupier and their financial responsibility and standing as the Landlord may reasonably require and the terms and conditions of the proposed instrument and shall deliver to the Landlord a counterpart of the assignment, transfer or sublease duly executed by the Tenant and the other party or parties thereto, which shall be conditional upon the Landlord's consent hereunder, and within fifteen (15) business days after the Tenant shall have delivered to the Landlord such executed counterpart and such information, the Landlord shall give written notice to the Tenant:

(a) that the Landlord consents thereto; or

(b) that the Landlord does not consent thereto; or

(c) that the Landlord elects to cancel this Lease in preference to the giving of such consent. In the event the Landlord elects to cancel this Lease as aforesaid, the Tenant shall notify the Landlord in writing within fifteen (15) days thereafter of the Tenant's intention either to refrain from such assigning, transferring, subletting or parting with or sharing possession, in which case the Landlord's election to cancel the Lease will be deemed revoked by the Landlord, or to accept the cancellation of this Lease; or

(d) that (if the Tenant has requested the Landlord's approval of a sublease or part of the Premises, in this subarticle (c) referred to as the "Space"), that the Landlord elects to sublease the Space from the Tenant upon the terms and conditions of the proposed sublease for which the Tenant requests the Landlord's consent except that;

(i) the rent payable under the Landlord's sublease of the Space shall be the lower of the Annual Base Rent apportioned pro rata to the rentable area of the Space or the rent payable under the proposed sublease for which the Tenant is requesting consent;

(ii) the Landlord shall at all times under such sublease have the right and option to sublet the Space of any part thereof without obtaining the Tenant's consent or sharing any of the economic consideration received by the Landlord thereunder;

(iii) no security deposit will be payable by the Landlord to the Tenant nor will other security require to be given by the Landlord to the Tenant for the performance of the Landlord's obligations under the sublease;

(iv) the Landlord and its subtenants shall have the right to use in common with the Tenant all washrooms, corridors, lobbies which are within the Premises and the use of which is reasonably required for the use of the Space;

(v) the Tenant shall have no right of set-off or abatement or any other right to assert a default hereunder by reason of any default of the Landlord under such sublease;

(vi) no successor to the Landlord's interest under this Lease shall be responsible for any liability or obligation of the Landlord under such sublease unless such successor is also an assignee of such sublease and then only if and to the extent that such liability and obligation runs with the land or is assumed by it,

provided that in the event the Landlord elects to sublease the Space from the Tenant, the Tenant shall notify the Landlord within fifteen (15) days thereafter of the Tenant's intention either to refrain from such subletting, in which case the Landlord's election to sublet the Space will be deemed revoked by the Landlord, or to accept the Landlord's sublease of the Space.

If the Tenant elects to accept such cancellation this Lease shall thereby be terminated on the forty-fifth (45th) day following delivery of the notice of the Tenant's election. Should the Tenant fail to deliver such notice within the last-mentioned period of fifteen (15) days, this Lease will thereby be terminated upon the forty-fifth (45th) day immediately following the expiration of the last-mentioned fifteen (15) day period and the Tenant will deliver up vacant possession of the Premises on such date of termination.

If the Landlord does not give such written notice to the Tenant, the Landlord will be deemed to have given written notice that it does not consent to the proposed assignment, transfer or sublease or parting with or sharing of possession or other proposed transaction referred to in this subarticle 12.2.

No such assignment, transfer, subletting or parting with or sharing of possession or other transaction referred to in this subarticle 12.2 shall:

(A) in any manner release the Tenant from its obligations for the payment of Rent and the observance and performance of the covenants, terms and conditions herein provided;

(B) be made to any person, firm, partnership, or corporation carrying on any business which the Landlord is obliged to restrict by reason of any other Lease or contract relating to the Building or the Lands and Premises; or

(C) be made to any person, firm, partnership or corporation which has carried on or is carrying on negotiations with the Landlord or its agents with respect to the leasing of premises in the Building.

12.3 Assumption by Assignee

Except upon any deemed assignment under subarticle 12.4, the Tenant shall deliver to the Landlord an instrument duly executed by the assignee, in form and substance satisfactory to the Landlord wherein the assignee shall assume the Tenant's obligations for the payment of Rent and for the full and faithful observance and performance of the covenants, terms and conditions to be observed and performed by the Tenant hereunder.

12.4 Change of Control is Deemed Assignment

Any transfer, creation, issuance, sale, assignment, bequest, inheritance, trust or other disposition or dealing with the shares or voting rights or amalgamation or other reorganization which results in a change in the control of the corporation by reason of ownership of greater than fifty percent (50%) of the voting shares of the corporation becoming held by a person or group of persons shall be deemed for the purposes hereof to be an assignment of this Lease. This subarticle 12.4 shall not apply with respect to the change of control of a corporation if control thereof is already represented by shares listed on a recognized security exchange.

12.5 Corporate Records

The Tenant shall, upon request of the Landlord, make available to the Landlord from time to time such documentation or other data that shows the applicability or inapplicability of subarticle 12.4 hereof. If any shareholder of the Tenant shall, upon request of the Landlord, fail or refuse to furnish to the Landlord any certified true copy of such data of such shareholder or other credible person, which data, alone or with other data show the applicability or inapplicability of subarticle 12.4 hereof then the Landlord may terminate this Lease on sixty (60) days' notice.

12.6 Landlord's Costs

In the event of an assignment or subletting or parting with or sharing of possession or conferring of rights under this Article 12, the Tenant shall forthwith pay to the Landlord as Additional Rent, the Landlord's reasonable legal fees, disbursements and expenses in connection therewith.

13. DEFAULT AND THE LANDLORD'S RIGHT TO CURE DEFAULT

13.1 Default

The Tenant covenants with the Landlord that:

(a) in the event of a breach, non-observance or non-performance of any covenant, agreement, stipulation, proviso, condition, rule or regulation herein contained on the part of the Tenant to be kept, performed or observed, which continues for fifteen (15) days after written notice thereof to the Tenant by the Landlord, or

(b) notwithstanding the foregoing, if any Rent whether demanded or not, is not paid when due, or

(c) if the Premises shall be vacated or remain unoccupied by fifteen (15) business days, or

(d) if the Term shall be taken in execution or attachment for any cause whatsoever, or

(e) if the Premises shall be used for any purpose not permitted hereunder without the written consent of the Landlord,

(Each an “Event of Default”) and if such Event of Default except for payment of Rent when no noticed is needed, has not been cured by the Tenant within fifteen (15) days after written notice thereof to the Tenant by the Landlord, then and in any such case and in addition to any other remedy now or hereafter provided under the terms hereof or at law or in equity:

(i) the Landlord may re-enter and take possession of the Premises or any part thereof in the name of the whole and have again, repossess and enjoy the Premises in the Landlord's former estate, anything herein to the contrary notwithstanding, as though the Tenant were holding over after the expiration of the Term; and the Term shall, at the option of the Landlord, forthwith become forfeited and determined; and any obligations of the Tenant accruing hereunder prior to the date of such re-entry and termination shall not be affected or in any way limited by such re-entry and termination but shall survive and the Tenant shall save harmless and indemnify the Landlord from any and all loss, costs, damages, claims and expenses which the Landlord may suffer or incur by reason of such termination of this Lease notwithstanding such termination;

(ii) the Landlord may re-let the Premises or any part thereof from time to time as the Tenant's agent and on the Tenant's account and in the Tenant's name, as the Tenant's agent, and for that purpose may enter the Premises or any part thereof in the name of the whole but without terminating this Lease upon given the Tenant written notice of the Landlord's intent to re-let the Premises under this subarticle (ii); and the Landlord shall apply the proceeds of such sale and any rent derived from re-letting the Premises, after deducting its costs of conducting such sale and its costs of re-letting, on account of the Rent under this Lease, and the Tenant shall be liable to the Landlord for the deficiency, if any.

(iii) the Tenant covenants and agrees that the failure by the Tenant to pay to the Landlord the amount of any Goods and Services Tax owing by the Tenant to the Landlord when due hereunder, shall constitute a default by the Tenant under this Lease and will entitle the Landlord to exercise any and all rights and remedies available to the Landlord for the recovery of Rent in arrears. The Tenant further covenants and agrees that if the Goods and Services Tax is not enacted as proposed or it is amended in such a manner that it imposes any additional financial obligations on the Landlord, the Tenant shall forthwith pay to the Landlord for all such additional financial obligations and the Tenant agrees to execute such agreements and documents as the Landlord may reasonably require in order to ensure that such additional financial obligations will be paid by the Tenant.

13.2 Re-Entry

Upon the Landlord becoming entitled to re-enter the Premises hereunder the Landlord may do so by reasonable force if necessary without any previous notice of intention to re-enter and may remove all persons and property therefrom and may use such reasonable force and assistance in making such removal as the Landlord may deem advisable to recover full and exclusive possession of the Premises and such re-entry shall not operate as a waiver or satisfaction in whole or in part of any right claim or demand arising out of or in connection with any breach, non-observance or non-performance of any covenant or agreement on the part of the Tenant to be kept, observed or performed hereunder.

13.3 Bankruptcy, Insolvency, Etc.

If:

(a) the Term or any of the goods and chattels of the Tenant shall at any time during the Term be seized or taken in attachment by any creditor of the Tenant, or if

(b) a writ of execution, sequestration or extent shall issue against the goods and chattels of the Tenant, or if

(c) the Tenant shall execute any chattel mortgage or bill of sale of its goods and chattels in the Premises (other than one incidental to any public issue of bonds, debentures or other securities of the Tenant or to any reorganization of the Tenant or its amalgamation with any other company), or if

(d) any petition or other application is filed in or presented to any court of competent jurisdiction for the dissolution, liquidation or winding up of the Tenant or for the appointment of a receiver or receiver and manager for the Tenant, or if

(e) the Tenant shall become bankrupt or insolvent or take the benefit of any statute now or hereafter in force for bankruptcy or insolvent debtors, or if

(f) the Tenant shall make an assignment for the benefit of creditors or shall make any sale or other disposition of goods and chattels which is governed by legislation relating to bulk sales (except one incidental to any reorganization of the Tenant, if any, or its amalgamation with any other company),

then and in every such case and in addition to any other remedy now or hereafter provided herein or which the Landlord may have at law or in equity:

(i) the Landlord shall have the rights and remedies and the Tenant shall have the obligations provided in subarticles 13.1(i) and (ii); and

(ii) the then current month's instalments of Annual Base Rent and of Operating Expenses and of Taxes and the next ensuing three (3) months' instalments of Annual Base Rent, Operating Expenses and Taxes shall become immediately due and payable.

13.4 Termination

The Tenant further covenants and agrees that on the Landlord becoming entitled to re-enter upon the Premises under any of the provisions of this Lease, the Landlord in addition to all other rights, shall have the right to determine forthwith this Lease and the Term by giving notice in writing to the Tenant of its intention so to do, and thereupon Rent shall be computed, apportioned and paid in full to the date of such determination of this Lease, and any other payments for which Tenant is liable under this Lease shall be paid and the Tenant shall forthwith deliver up possession of the Premises to the Landlord and the Landlord may re-enter and take possession of same.

13.5 Distress

Whenever the Landlord shall be entitled to levy distress against the goods and chattels of the Tenant it may use such force as it may deem necessary for the purpose and for gaining admission to the Premises without being liable for any action in respect thereof or for any loss or damage occasioned thereby and the Tenant hereby expressly releases the Landlord from all actions, proceedings, claims, or demand whatsoever for or on account or in respect of any such forcible entry or any loss or damage sustained by the Tenant in connection therewith. The Tenant waives and renounces the benefit of any present or future statute taking away or limiting the Landlord's right of distress, and covenants and agrees that notwithstanding any such statute none of the goods and chattels of the Tenant on the Premises at any time during the Term shall be exempt from levy by distress for rent in arrears.

13.6 Landlord's Right to Perform

If the Tenant shall fail to observe or perform any of the covenants or obligations of the Tenant under or in respect of this Lease the Landlord may from time to time at its discretion perform or cause to be performed any of such covenants or obligations or any part thereof and for such purpose may do such things as may be requisite and may enter upon the Premises to do such things and all expenses incurred and expenditures made by or on behalf of the Landlord shall be forthwith paid by the Tenant to the Landlord; provided that if the Landlord commences or completes either the performance or the causing to be performed of any such covenants or obligations or any part thereof, the Landlord shall not be obliged to complete such performance or causing to be performed or be later obliged to act in like fashion.

13.7 Remedies Cumulative

No remedy conferred upon or reserved to the Landlord herein, by statute or otherwise, shall be considered exclusive of any other remedy, but the same shall be cumulative and shall in addition to every other remedy available to the Landlord and all such remedies and powers of the Landlord may be exercised concurrently and from time to time and as often as may be deemed expedient by the Landlord.

13.8 Interest on Arrears

The Tenant shall pay to the Landlord interest at the rate of one and one-half percent (1-1/2%) per month compounded monthly in arrears (19.56% per annum), on any amount not paid as and when due hereunder, until paid, whether or not demand be made therefor.

13.9 Late Charges

The Tenant acknowledges that late payment of Rent will cause the Landlord to incur costs not contemplated by this Lease, the exact amount of such costs being extremely difficult and impracticable to fix. Such costs include, without limitation, processing and accounting charges and late charges that may be imposed on the Landlord by the terms of any encumbrance and note secured by any encumbrance covering the Premises. Therefore, if any Rent due from the Tenant is not received by the Landlord within five (5) days after the same becomes due, the Tenant shall pay to the Landlord on demand the Landlord's out of pocket expenses incurred in obtaining or attempting to obtain payment of the amount in arrears and in addition the Tenant agrees to pay to the Landlord as a late charge with respect to each amount of Rent in arrears after expiry of the five (5) day grace period either:

(a) five percent (5%) of the amount in arrears at the end of the five (5) day grace period; or

(b) Twenty-Five Dollars ($25)

whichever is the greater, and such amount shall become payable immediately on expiry of the five (5) day grace period with respect to the amount becoming in arrears and shall thereafter be calculated and become payable on the sixth (6th) day of each and every month with respect to the aggregate amount in arrears so long as any Rent remains in arrears. The parties agree that this late charge represents a fair and reasonable estimate of the costs that the Landlord will incur by reason of such late payment by the Tenant. Acceptance of any late charges shall not constitute a waiver of the Tenant's default with respect to the overdue amount, or prevent the Landlord from exercising any of the other rights and remedies available to the Landlord.

14. INDEMNIFICATION AND WAIVER OF LIABILITY

14.1 Waiver of Liability

The Landlord shall not be liable or responsible in any way for, and the Tenant hereby waives all claims against the Landlord with respect to or arising out of:

(a) any death or injury of any nature whatsoever that may be suffered or sustained by the Tenant or by any employee, licensee, invitee, guest, agent or customer of the Tenant or by any other person upon the Premises, from any causes whatsoever; or for any loss or damage or injury to any property outside or within the Premises belonging to the Tenant or its

employees, agents, customers, licensees, invitees, guests or any other person, whether or not such damage, loss, injury or death results from the negligence of the Landlord, its agents, servants or employees or others for whom the Landlord is, in law, responsible;

(b) any injury or damages of any nature whatsoever to persons or property caused by explosion, fire, theft or breakage, by the failure of or defect in sprinkler, drainage or plumbing systems, by failure for any cause to supply adequate drainage, by the interruption of any public utility or service, by steam, gas, water, rain, snow or other substances leaking, issuing or flowing into any part of the Premises, or by nature occurrence, acts of the public enemy, riot, strike, insurrection, war, court order, requisition or order of governmental body or authority;

(c) any damage or inconvenience which may arise from repair, maintenance or alteration of any part of the Building, or anything done or omitted to be done by any tenant, occupant or person in the Building, or by an occupant of adjacent property, or by the public, or by construction of any private, public or quasi-public work;

(d) the occurrence of any of the perils covered by, or which would be covered by, the insurance policies which the Tenant is obliged to obtain and maintain in force under the terms of this Lease;

(e) any act or omission (including theft, malfeasance or negligence) on the part of any agent, contractor or person from time to time employed by the Landlord to perform any services including, without limitation, janitorial or security services, in or about the Premises or the Building;

(f) any loss or damage however caused, to money, securities, negotiable instruments, papers or other valuables of or held by the Tenant or any employee, licensee, invitee, guest, agent or customer of the Tenant or by any other person upon the Premises;

(g) theft or vandalism;

whether caused by the act, omission or negligence of the Landlord or of any other person for whom the Landlord is in law responsible or otherwise.

14.2 Tenant to Indemnify Landlord

The Tenant does hereby covenant to save harmless and indemnify the Landlord from and against all liability, expense, costs, damages, losses, claims, actions, causes of action and fines incurred or suffered by the Landlord:

(a) by reason of any breach, violation, non-observance or non-performance by the Tenant, its servants, agents or others for whom the Tenant is, in law, responsible of any covenant, agreement, provision or condition of this Lease to be performed or observed by the Tenant including without limitation the Rules and Regulations, or

(b) by reason of any damage to or loss of any property or injury, illness or death to any person (including without limitation, the Tenant):

(i) occurring in, on, or about the Premises, or any part thereof, arising at any time from any cause whatsoever other than solely by reason of the gross negligence or willful misconduct of the Landlord, its employees or agents; and

(ii) occurring in, on, or about any part of the Building other than the Premises, when such damage, loss, injury, illness or death shall be caused in whole or in part by the negligence or willful misconduct of the Tenant, its agents, servants, employees, invitees or licensees (including, without limitation, when such damage, injury, illness or death shall have been caused in part by the Landlord, its employees or agents).

14.3 Survival of Covenants

The provisions of this Article 14 shall survive the termination of this Lease with respect to any damage, injury, illness or death or other event occurring prior to such termination.

15. INSURANCE

15.1 Landlord Insurance

The Landlord shall take out and maintain in full force and effect insurance against all risks of physical loss or damage to the Building and such fixtures and improvements as the Landlord shall

determine, including if and to the extent reasonably available in the Greater Vancouver area at reasonable rates, the perils of flood and earthquake, and including business interruption or loss of rental income insurance, in amounts equal to the full insurable value thereof calculated on a replacement cost basis, and subject to such deductibles as the Landlord may reasonably determine, provided however that the "full insurable value" as described above shall not include, and the Landlord's policies of insurance shall not cover, any property of the Tenant, whether owned by the Tenant or held by it in any capacity, nor any Alterations.

15.2 Tenant's Insurance

The Tenant covenants and agrees to take out and maintain in full force and effect throughout the Term the following insurance forms, amounts and with insurance carriers satisfactory to the Landlord:

(a) comprehensive bodily injury and property damage liability insurance applying to the operations of the Tenant carried on from the Premises, which shall include personal injury liability, product liability, contractual liability, non-owned automobile liability and protective liability with respect to the occupancy of the Premises by the Tenant, and such insurance shall be written for an amount of not less than Five Million ($5,000,000) Dollars per occurrence, or such higher amount as the Landlord may from time to time reasonably require. Such limits may be reached through use of primary or excess policies or a combination thereof;

(b) tenant's all risks legal liability insurance in an amount equal to not less than the replacement cost of the Premises;

(c) insurance against all risks of physical loss or damage on Tenant's fixtures, Alterations, stock in trade, furniture, and all other contents of the Premises, in an amount equal to not less than the full replacement cost thereof; and

(d) any other insurance in a form, amount and for insurance risks as the Landlord or the Landlord's Mortgagee may reasonably require from time to time.

The Tenant shall renew each such insurance policy no later than the same day as the expiration of its policy term and shall, no later than the day of expiration of the previous policy term, forward to the Landlord certificates of insurance evidencing the policies in effect. Each such certificate shall contain sufficient information to verify the Tenant's obligation contained herein. Except for tenant's all risk legal liability insurance, each applicable policy shall name the Landlord and the Landlord's Mortgagee as additional insureds as their interests may appear, and shall contain Schedule "D" hereto. In the case of public liability insurance, the policy shall contain a provision for cross liability as between the Landlord and the Tenant. Each such policy shall provide that the insurer shall not have any right of subrogation against the Landlord on account of any loss or damage covered by such insurance or on account of any payments made to discharge claims against or liabilities of the Landlord or the Tenant covered by such insurance. Each such policy shall be non-contributing with, and shall apply only as primary and not excess to, any other insurance available to the Landlord, and each such policy shall provide that the insurance coverage shall not be invalidated with respect to the Landlord's interest by reason of the acts or omissions of the Tenant. The Tenant shall obtain from the insurers under each policy of insurance, undertakings to notify the Landlord in writing at least thirty (30) days prior to the cancellation or material change of any such policies.

15.3 Tenant's Actions Affecting Insurance

The Tenant shall not do or permit anything to be done or exist upon the Premises whereby any policy of insurance against loss or damage to the Premises or against legal liability for damage to persons or property arising from the ownership, maintenance, use or occupancy of the Premises or by reason of the conduct of any business carried out therein, may be restricted or invalidated and, for such purpose, upon receipt of notice in writing from any insurer of the Premises requiring the execution of works or a discontinuance of any operations in order to correct such situation, the Tenant shall comply therewith promptly and in any event within forty-eight (48) hours after such notice or before such policy is invalidated, whichever is the shorter period.

The Tenant shall repay to the Landlord, on demand, from time to time as Additional Rent an amount equal to the increase in the rate of premium for such insurance above the usual rate of premium for such insurance resulting from anything done or existing upon the Premises. In determining whether increased premiums are a result of the Tenant's use or occupancy of the Premises, a schedule issued by the insurer under such policy or by its agent computing the premium and showing the various components of such premium shall be conclusive evidence of the items and charges which make up such premium and of the basis upon which such premium is calculated.

15.4 Cancellation of Insurance

If any insurer under any insurance policy covering any part of the Building or any occupant thereof cancels or threatens to cancel its insurance policy or reduces or threatens to reduce coverage under

such policy by reason of the use of the Premises by the Tenant or by any assignee or subtenant or the Tenant, or by anyone permitted by the Tenant to be upon the Premises, the Tenant shall remedy such condition promptly, and in any event within forty-eight (48) hours after Notice thereof by the Landlord.

16. DAMAGE AND DESTRUCTION

16.1 Abatement or Termination

If the Premises or Building are damaged or destroyed in whole or in part by fire or any other occurrence, then, except as provided in this Article, this Lease shall continue in full force and effect and there shall be no abatement of Rent.

If the Premises are at any time destroyed or damaged as a result of fire or any other casualty required to be insured against by the Landlord under this Lease or otherwise insured against by the Landlord, then the following provisions shall apply:

(a) if the Premises are rendered untenantable in whole or in part, the Landlord shall diligently repair the Premises to the extent only of its obligations under this Lease;

(b) if the Premises are rendered untenantable in whole or in part by any event which has not been caused or contributed to by the Tenant or its employees, agents or licensees or anyone from whom the Tenant is in law responsible, Annual Base Rent (but no other Rent) shall abate in proportion to the part of the Premises (excluding Alterations) rendered untenantable and from time to time remaining unrepaired by the Landlord as herein required from the date of their being rendered untenantable until the Landlord's repairs have been completed so that such abatement shall cease with respect to any portion of the Premises in respect of which the Landlord's repairs have been completed;

(c) if the Premises are not rendered untenantable in whole or in part, the Landlord shall diligently perform such repairs to the Premises to the extent only of its obligations under this Lease, but in such circumstances Rent shall not terminate or abate;

(d) upon being notified by the Landlord that the Landlord's repairs have been substantially completed or when damaged parts of the Premises are turned over by the Landlord to the Tenant for making of the Tenant's Alterations the Tenant shall diligently perform all repairs to the Premises which are the Tenant's responsibility under this Lease and all other work required to fully restore the Premises for use in the Tenant's business, in every case at the Tenant's cost and without any contribution to such cost by the Landlord, whether or not the Landlord has at any time made any contribution to the cost of supply, installation or construction of Leasehold Improvements in the Premises; and

(e) nothing in this Lease requires the Landlord to rebuild the Building, including without limitation the Premises, in the condition which existed before any such damage or destruction so long as the Building, including without limitation the Premises, as rebuilt will have reasonably similar facilities to those in the Building, including without limitation the Premises, prior to such damage or destruction, having regard, however, to the age of the Building at such time.

Notwithstanding the foregoing, in the event of damage to the Premises or the Building, the Landlord's covenants as set out above shall only apply to the extent that insurance proceeds are available to the Landlord for the repair or rebuilding thereof.

16.2 Right of Termination

Notwithstanding anything contained in this Lease, if the damage or destruction which has occurred in the Premises is such that in the reasonable opinion of the Landlord the Premises cannot be rebuilt or made fit for the purposes of the Tenant within one hundred eighty (180) days of the happening of the damage or destruction, the Landlord may, at its option, terminate this Lease on notice to the Tenant given within sixty (60) days after such damage or destruction. If such notice of termination is given, Rent shall be apportioned and paid to the date of such damage or destruction and the Tenant shall immediately deliver vacant possession of the Premises in accordance with the terms of this Lease.

16.3 Destruction of or Damage to the Building

Notwithstanding any other provision of this Lease, if

(a) the Landlord determines that the Building is damaged or destroyed in whole or in part (whether or not the Premises are also damaged or destroyed) and it is not economically feasible to repair or reconstruct; or

(b) the Building or the Lands or any other improvements on the Lands which affect access or services essential thereto are damaged or destroyed in whole or in part and, in the reasonable opinion of the Landlord, cannot reasonably be repaired within one hundred eighty (180) days after the occurrence of the damage or destruction,

the Landlord may, by notice to the Tenant given within sixty (60) days of such damage or destruction, terminate this Lease, in which event neither the Landlord not the Tenant shall be bound to repair and the Tenant shall surrender the Premises to the Landlord within thirty (30) days after delivery of such notice and Rent accruing hereunder (except Tenant Taxes) shall be apportioned and paid to the date on which the Tenant delivers vacant possession of the Premises, subject to any abatement to which the Tenant may be entitled under subarticle 16.2; and the Tenant shall pay to the Landlord on the date of termination that fraction of the Tenant Inducement which has:

(i) as its numerator the number of days remaining in the Term; and

(ii) as its denominator the number of days in the Term as originally provided herein.

If the Landlord is entitled to terminate this Lease under this Article but does not elect to do so, the Landlord shall, following such damage or destruction, diligently repair if necessary that part of the Building damaged or destroyed, but only to the extent of the Landlord's obligations under the terms of the various leases for premises in the Building and exclusive of

any tenant's responsibilities with respect to such repair, and only to the extent that insurance proceeds are available to the Landlord for the repair thereof. If the Landlord elects to repair the Building, the Landlord may do so in accordance with plans and specifications other than those used in the original construction of the Building.

16.4 Architect's Certificate

The certificate of the Landlord's Architect shall bind the parties as to:

(a) whether or not the Premises or any part thereof are rendered untenantable;

(b) when either the Landlord's or Tenant's work of reconstruction or repair is completed or substantially completed;

(c) when the Premises or any part thereof are rendered tenantable.

17. COSTS OF PROFESSIONAL SERVICES

If the Landlord shall retain the services of a lawyer or any other person for the purpose of enforcing the Landlord's rights or protecting its interests with respect to this Lease or the Premises or any act or omission of the Tenant or in connection with any consent or other agreement requested by the Tenant, the Tenant shall pay to the Landlord the cost as Additional Rent of all such services including those relating to court proceedings at trial or on appeal on a "lawyer and own client" basis.

18. SURRENDER OF PREMISES

At the expiry or earlier termination of this Lease, the Tenant shall peaceably deliver up to the Landlord possession of the Premises, together with all Alterations in the same condition as received, or first installed, reasonable wear and tear excepted. The Tenant may, prior to or upon the termination of this Lease, remove all movable partitions of less than full height from floor to ceiling and all furnishings required by the Tenant, repairing any damage caused by such removal. Property not so removed shall be deemed abandoned by the Tenant and title to the same shall thereupon pass to the Landlord. Upon request by the Landlord, the Tenant, at its cost, shall prior to the termination of the Lease remove any or all Alterations and all such movable partitions and furnishings which may not be required by the Tenant and repair any damage resulting from such removal. Without limiting the generality of the foregoing the Tenant will, at the expiry or earlier termination of this Lease and at its sole cost and expense, restore the Premises and the Building to their condition prior to the making of any Alterations, except as may be otherwise approved in writing by the Landlord. All work required under this Article 18 shall be completed prior to the expiry or earlier termination of the Term.

19. HOLDING OVER

If the Tenant shall remain in possession after the expiration or earlier termination of this Lease, all of the terms, covenants and agreements to be observed and performed by the Tenant hereunder shall continue to apply and bind the Tenant so long as the Tenant shall remain in possession insofar as the same are applicable, except that if the Tenant remains in possession without the Landlord's written consent, the monthly Rent payable under articles 4.1(a), (b) and (c) shall be two (2) times the Rent payable for the last month of the Term, prorated on a daily basis for each day that the Tenant remains in possession of any part of the Premises and the Tenant shall indemnify the Landlord against any and all claims, losses and liabilities for damages resulting from failure to surrender possession, including, without limitation, any claims made by any succeeding tenant. If the Tenant remains in possession of the Premises or any part thereof without

the Landlord's written consent, the Tenant's obligations under this Article 19 shall accrue so long as the Tenant shall remain in possession of the Premises or any part thereof notwithstanding the Landlord's right to possession of the Premises and notwithstanding any and all proceedings or actions of the Landlord in an effort to recover possession of the Premises.

If the Tenant remains in possession with the Landlord's written consent, such tenancy shall be from month to month, terminable by either party on one (1) month's written notice.

20. WAIVER

The failure of the Landlord to exercise any right or option in connection with any breach or violation of any term, covenant or condition herein contained shall not be deemed to be a waiver or release of such term, covenant, or condition or any subsequent breach of the same or any other term, covenant or condition herein contained. The subsequent acceptance of Rent hereunder by the Landlord shall not be deemed to be a waiver of a preceding breach by the Tenant of any term, covenant or condition of this Lease other than the failure of the Tenant to pay the amount so accepted, regardless of the Landlord's knowledge of such preceding breach at the time of acceptance of such rental.

The execution and delivery of this Lease does not waive any default of the Tenant then existing whether known to the Landlord or otherwise. No waiver of any right of the Landlord shall be effective unless in writing.

21. SUCCESSORS

21.1 Successors

All the terms, covenants and conditions hereof shall be binding upon and enure to the benefit of the successors and assigns of the Landlord and the successors and permitted assigns of the Tenant.

21.2 Successors of the Landlord

The term "Landlord" as used in this Lease so far as covenants or obligations on the part of the Landlord are concerned shall be limited to mean Landlord as hereinbefore set out, while it retains its interest in the Lands and Premises but upon a sale, transfer or other disposition of that interest, the Landlord shall be automatically relieved after the date of such sale, transfer or other disposition of all liability arising out of the requirement for performance of any obligations on the part of the Landlord herein contained, it being understood and agreed that the obligations of the Landlord contained in this Lease shall be binding upon each party from time to time constituting the Landlord only during and in respect of the period of their respective interests in the Lands and the Premises.

22. ATTORNMENT

22.1 Attorn Tenant to Owners, Purchaser or Lessee

The Tenant shall promptly on request attorn tenant to the owners of the Building and the Lands, or the lessee under any ground, operating, overriding, underlying or similar lease granted by the Landlord or the purchaser from the Landlord and shall recognize such owner, lessee or purchaser as the landlord under this Lease.

22.2 Attorn Tenant to Landlord's Mortgagee or Purchaser

Without limiting the generality of the foregoing, whenever required by any mortgagee, debenture holder or a trustee on behalf of a mortgagee (herein called the "Landlord's Mortgagee"), under any mortgage, the Tenant shall attorn to and become a tenant or lessee of such Landlord's Mortgagee taking title to the Lands upon any foreclosure; and, on any purchase from such Landlord's Mortgagee in the event of an exercise by such Landlord's Mortgagee of the power of sale in the mortgage set out, the Tenant shall attorn tenant to the purchaser of the Building and the Lands, in each case, for the then unexpired residue of the Term upon all the terms and conditions hereof.

23. ESTOPPEL CERTIFICATE

At any time and from time to time, within ten (10) days after written request by the Landlord or upon the date designated by the Landlord being no less than ten (10) days after written request by the Landlord, the Tenant shall complete and execute under seal and deliver to the Landlord, a certificate addressed to the Landlord and to such other person or persons or corporation or corporations as the Landlord shall designate certifying in such form as the Landlord may reasonably request:

(a) that the Tenant has accepted the Premises (of, if the Tenant has not done so, that the Tenant has not accepted the Premises, and specifying the reasons therefor);

(b) the Commencement Date and the expiration date of this Lease;

(c) whether there are then existing any defaults by the Landlord in the performance of its obligations under this Lease (and, if so, specifying the same);

(d) that this Lease is unmodified and in full force and effect (or, if there have been modifications, that this Lease is in full force and effect, as modified, and stating the date and nature of each modification);

(e) the capacity of the person executing such certificate, and that such person is duly authorized to execute the same on behalf of the Tenant;

(f) the amount of Rent then being paid hereunder;

(g) the date, if any, to which rent and other sums payable hereunder have been paid;

(h) whether the Tenant claims any right of set-off or abatement hereunder and, if so, stating in reasonable detail the amount, nature and other particulars thereof;

(i) that no notice has been received by the Tenant of any default which has not been cured, except as specified in the certificate; and

(j) the amount and other particulars of any security deposit and prepaid Rent;

(k) such other matters as may reasonably be requested by the Landlord;

and stating that the certificate may be relied upon by the addressees in any transaction relating to the Lands, the Building, the Premises and this Lease or any one or more of them; and any such certificate may be relied upon by any prospective purchaser or mortgagee and by each beneficiary under any deed of trust affecting the Building or any part thereof. If the Tenant fails to complete and deliver the executed certificate when required hereunder, the Tenant irrevocably constitutes and appoints the Landlord as its special attorney in fact to execute and deliver the certificate to any third party.

24. SUBORDINATION

24.1 Subordination of this Lease

This Lease shall be subject and subordinated at all times to:

(a) all ground or underlying leases of the Land or the Building which may now exist or hereafter be executed; and

(b) the lien of all mortgages including any mortgage now existing or hereafter placed on or against the Land or the Building, or on or against the Landlord's interest or estate therein, or on or against the Landlord's interest in and to all such ground or underlying leases, all without the necessity of having further instruments executed on the part of the Tenant to effectuate such subordination.

Notwithstanding the foregoing:

(i) in the event of termination for any reason whatsoever of any such ground or underlying lease, and if such ground or underlying lease so provides, then this Lease shall not be barred, terminated, cut off or foreclosed, nor shall the rights of the Tenant hereunder be disturbed if the Tenant shall not then be in default in the payment of rental or other sums or be otherwise in default under the terms of this Lease, and the Tenant shall attorn to the Landlord of any such terminated ground or underlying lease, or, if requested, enter into a new lease for the balance of the Term then remaining, upon the same terms and provisions as are contained in this Lease and surrender this Lease;

(ii) in the event of a foreclosure of any such mortgage or deed of trust or of any other action or proceeding for the enforcement thereof, or of any sale thereunder, and if any such mortgage or deed of trust so provides, this Lease will not be barred, terminated, cut off or foreclosed, nor will the rights of the Tenant hereunder be disturbed if the Tenant shall not then be in default in the payment of rental or other sums or be otherwise in default under the terms of this Lease, and the Tenant shall attorn to such foreclosing mortgagee or to the purchaser at such sale, as the case may be, if requested, enter into a new lease with such purchaser for the balance of the Term then remaining upon the same terms and provisions as are contained in this Lease and surrender this Lease.

The Tenant agrees to execute and deliver upon demand such documents evidencing the subordination of this Lease to such deed, to such ground or underlying leases, and to the lien of any such mortgage or deeds of trust as may reasonably be required by the Landlord.

If the Tenant fails to execute and deliver any such documents the Tenant irrevocably constitutes and appoints the Landlord as the Tenant's attorney in fact to execute and deliver such documents or instruments.

24.2 Subordination of Mortgage

Notwithstanding anything to the contrary set forth above, the holder of any mortgage (including without limitation any deed of trust) may at any time subordinate its mortgage to this Lease in whole or in part, without any need to obtain the Tenant's consent, by execution of a written document subordinating such mortgage to this Lease to the extent set forth in such document and thereupon this Lease shall be deemed prior to such mortgage to the extent set forth in such document without regard to their respective dates of execution, delivery and/or registration and without regard to whether this Lease and such mortgage or either of them may not have been registered in any office of public record or may not be in registrable form or in form suitable for recording in any such office. In that event, to the extent set forth in such document, such mortgagee shall have the same rights with respect to this Lease as would have existed if this Lease had been executed and recorded or registered in all appropriate offices of public record prior to the execution, delivery and recording of the mortgage.

25. RELOCATION

The Landlord will have the right to require the Tenant to vacate the Premises and to surrender the leasehold interest hereby created so far as it relates to the Premises with effect as at any date during the Term on the following terms and conditions:

(a) the Landlord may exercise its right under this Article by giving the Tenant no less than ninety (90) days' written notice (the "Relocation Notice") of the date (referred to in this Article as the "Effective Date") on which the Tenant will be required to vacate the Premises and providing particulars of the other matters required to be dealt with in accordance with the following provisions of this Article;

(b) the Landlord will provide the Tenant with alternate premises in the Building (which alternate premises are herein called the "New Premises");

(c) the utility of the New Premises, including the improvements therein, shall be either substantially the same in area and layout (but need not have the same orientation) as the Premises or for a larger usable area than the Premises at no additional cost to the Tenant; and if the New Premises are not in that condition when the Relocation Notice is given, then the New Premises will be brought into that condition by the Landlord on or before the Effective Date at the sole cost and expense of the Landlord; Notwithstanding the generality of the foregoing, unless the Landlord obtains the prior written consent of the Tenant, the floor of the Building that the New Premises is located on shall be on at least the same floor of the Building as the Premises. In no case shall the New Premises be lower than floor 7;

(d) unless the Landlord obtains the prior written consent of the Tenant, the New Premises shall not be materially smaller than the Premises hereby demised, and if such consent of the Tenant is obtained, then the Annual Base Rent hereof shall be reduced in proportion to the reduction in the Rentable Area of the New Premises;

(e) the Tenant will execute an indenture supplemental to this Lease by which

(i) the Tenant will surrender its leasehold interest in the Premises with effect as at the Effective Date;

(ii) the Landlord will accept that surrender;

(iii) such surrender shall be without prejudice to the rights and remedies of the Landlord and the Tenant accruing on or before the Effective Date and without waiver of any default then existing under the Lease or of the rights and remedies of the Landlord with respect to any default existing on the Effective Date; and by which all such rights, remedies and defaults shall continue after the Effective Date as if the New Premises had been the premises demised by this Lease when any default occurred under this Lease and throughout the Term hereby granted; and

(iv) the provisions of this Lease, save as otherwise herein expressly provided, shall apply with respect to the New Premises as fully and effectively from and after the Effective Date as if the New Premises had been the premises hereby demised;

(f) the supplemental indenture shall be in such form as the Landlord may reasonably require and shall be executed by the Tenant and delivered to the Landlord prior to the Effective Date and shall thereupon promptly be executed and delivered to the Landlord;

(g) if the parties hereto shall agree that any of the particulars provided for in the Relocation Notice shall be amended or supplemented in any way during the period between the giving of the Relocation Notice and the Effective Date, the Relocation Notice shall remain effective and there shall be no change in the Effective Date unless the parties shall specifically agree in writing to a change in the Effective Date;

(h) the Landlord will pay to the Tenant by way of reimbursement to the Tenant all reasonable costs actually incurred by the Tenant as a result of the relocation arising under this Article 25 including without limitation costs incurred in changing the Tenant's stationery and business cards ~~and other like expenses but excluding~~ any lost revenue or other intangible costs; and other like expenses, and the Landlord will change the Building Directory; and

(i) the moving of the Tenant from the Premises to the New Premises shall take place on a weekend, if practicable, and shall be accomplished as quickly as is reasonably practicable.

26. NOTICES

All notices and demands which may be given or are required to be given by either party to the other hereunder shall be in writing and shall be deemed to have been fully given:

(a) to the Tenant if delivered either to the Premises or to the Tenant's address for notices set out in Article 1, or to such other place as the Tenant may from time to time designate by notice to the Landlord;

(b) to the Landlord at the address specified in Article 1, or to such other place as the Landlord may from time to time designate by notice to the Tenant. The Tenant hereby appoints as its agent to receive service of all proceedings and notices hereunder the person in charge of or occupying the Premises at the time, and if no person shall identify himself as being in charge of or occupying the same, then such service may be made by attaching the same to the main entrance to the Premises.

27. MISCELLANEOUS

27.1 Captions

The captions and headings of the Articles, subarticles and clauses in this Lease are for convenience only and shall not in any way limit or effect or be taken into account in construing or interpreting this Lease or any of the terms and provisions hereof.

27.2 Time of Essence

Time is of the essence of this Lease and of all provisions hereof, except in respect to the delivery of possession of the Premises at the commencement of the Term hereof.

27.3 Number and Gender; Joint and Several Liability

The words "Landlord" and "Tenant", as used herein, shall include the plural as well as the singular. Words used in the masculine gender include the feminine and neuter and vice versa. Words used in the singular include the plural and vice versa. If there be more than one Landlord or Tenant the obligations hereunder imposed upon the Landlord and Tenant shall be joint and several. The obligations of the Tenant and its permitted assigns shall be joint and several. References to persons includes references to corporations and other legal entities.

27.4 Governing Law

This Lease shall be construed and enforced in accordance with the laws of the Province where the Building is located.

27.5 No Offer

No contractual or other rights shall exist between the Landlord and the Tenant as a result of the negotiation of this Lease until both have executed and delivered this Lease, notwithstanding that rental deposits have been received by the Landlord and notwithstanding that the Landlord has delivered to the Tenant an unexecuted copy of this Lease. The submission of this Lease to the Tenant shall be for examination purposes only, and does not and shall not constitute a reservation of or an option for the Tenant to lease, or otherwise create any interest by the Tenant in the Premises or any other Premises situate in the Building. Execution of this Lease by the Tenant and return to the Landlord shall not be binding upon the Landlord,

notwithstanding any time interval, until the Landlord has in fact executed and delivered this Lease to the Tenant.

27.6 Entire Agreement

The terms of this Lease are intended by the parties as a final expression of their agreement with respect to such terms as are included in this Lease and may not be contradicted by evidence of any prior or contemporaneous agreement; and this Lease constitutes the complete and exclusive statement of its terms and no extrinsic evidence whatsoever may be introduced in any judicial proceedings, if any, involving this Lease; provided however that the provisions of any agreement between the parties hereto as to the performance of any work with respect to the Premises shall survive the execution and delivery of this Lease to the extent that such work and the obligations of the parties hereto relating to such work have not been fully performed at the date of execution and delivery of this Lease.

27.7 Invalidity

If any provision of this Lease or the application thereof to any person or to or in any circumstance, shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision to persons or to or in any circumstances other than those as to or in which it is invalid or unenforceable, shall not be affected thereby, and each provision of this Lease shall be valid and be enforced to the full extent permitted by law.

27.8 Authority

If the Tenant signs as a corporation or a partnership, each of the persons executing this Lease on behalf of the Tenant does hereby covenant and warrant that the Tenant is a duly authorized and existing entity, that the Tenant has and is qualified to do business in the Province in which the Building is located, that the Tenant has full right and authority to enter into this Lease, and that each of the persons signing on behalf of the Tenant are authorized to do so. Upon the Landlord's request, the Tenant shall provide the Landlord with evidence reasonably satisfactory to the Landlord confirming the foregoing covenants and warranties.

27.9 No Representations or Warranties

Neither the Landlord nor the Landlord's agents or attorneys have made any representations or warranties with respect to the Premises, the Building or this Lease, except as expressly set forth herein, and no rights, easements or licenses are or shall be acquired by the Tenant by implication or otherwise.

27.10 Management

The Landlord reserves the right to manage the Building using its own employees or an affiliate of the Landlord or to engage an independent management company.

27.11 Amendments

This Lease may not be altered, changed or amended except by an instrument executed under seal by all parties hereto.

27.12 No Light, Air or View Easement

Any diminution or shutting off of light, air, line of transmission or view by any structure which is now or may hereafter be erected on lands adjacent to the Building or elsewhere shall in no way affect this Lease or impose any liability on the Landlord. Noise, dust or vibration or other incidents to construction of improvements on lands adjacent to the Building, whether or not by the Landlord, shall in no way affect this Lease or impose any liability on the Landlord.

27.13 No Merger

The voluntary or other termination of this Lease shall not work a merger, and shall, at the option of the Landlord, either terminate any or all existing subleases or subtenancies, or operate as an assignment to the Landlord of any or all of such subleases or subtenancies.

13.14 No Admission of Status

The acceptance of any Rent from or the performance of any obligation hereunder by a person other than the Tenant shall not be construed as an admission by the Landlord of any right, title or interest of such person as a subtenant, assignee, transferee or otherwise in the place and stead of the Tenant.

13.15 No Registration

The Tenant covenants and agrees with the Landlord that the Landlord shall not be obliged to execute or deliver this Lease in form registrable under the Land Title Act or any other statute in pari materia therewith and that the Tenant will not register or record this Lease against the title to the Lands and Premises.

If the Tenant or any person claiming through or under him, whether by descent, purchase or otherwise, shall apply to have this Lease registered against the title to the Premises or the Lands or cause or permit any such application to be made or shall apply to file or register any notice of or caveat with respect to this Lease or the interest of the Tenant arising hereunder against such title or shall institute any proceedings to effect any such registration, the Landlord may at any time hereafter terminate this Lease and the Term hereby granted upon giving written notice of such termination to the Tenant.

27.16 Energy Conservation

The Tenant will co-operate with the Landlord, within reason, in the conservation of all forms of energy in the Building, including without limi the Premises.

The Tenant will comply with all laws, by-laws, regulations and orders relating to the conservation of energy and affecting the Premises or the Building.

The Tenant will at its own cost and expense comply with all reasonable requests and demands of the Landlord made with a view to such energy conservation.

All costs and expenses paid or incurred by the Landlord in complying with such laws, by-laws, regulations and orders, so far as the same shall apply to or reasonably be apportioned to the Building by the Landlord, shall be included in the Operating Expenses. The Landlord shall not be liable to the Tenant in any way for any loss, costs, damages or expenses whether direct or consequential, paid, suffered or incurred by the Tenant as a result of any reduction in the services provided by the Landlord to the Tenant or to the Building as a result of the Landlord's compliance with such laws, by-laws, regulations or orders.

27.17 Definition of Premises

In this Lease "Premises" means and shall be deemed to include (except where such meaning would be clearly repugnant to the context) the space demised and all Alterations therein. The space demised shall consist of the area shown hatched on Schedule "A" and shall be bounded by the unfinished interior surfaces of the perimeter walls and windows, the unfinished surfaces of interior load-bearing walls, the unfinished top of the floor slab and the unfinished bottom of the floor slab of the floor above, excluding, however, any stairs and other areas within said boundaries which are not included in the calculation of Premises Rentable Area, and excluding pipes, wires, ducts, conduits and other elements of the Building Systems constructed and installed by or for the Landlord including without limitation the HVAC System.

"Building Systems" means water, electric, telephone and other utility lines, wires, ducts, conduits and other facilities serving other portions of the Building which may pass through the space demised, the air-conditioning ducts and equipment, ceiling and ceiling light fixtures if of the standard type furnished by the Landlord, and sprinkler systems. The Landlord reserves the right to install, repair, replace, maintain and remove Building Systems in whole or in part.

27.18 Indemnity Agreement

[Intentionally Deleted]

27.19 Quiet Enjoyment

If the Tenant pays all Rent and fully observes and performs all of its obligations under this Lease, the Tenant shall be entitled to peaceful and quiet enjoyment of the Premises for the Term without interruption or interference by the Landlord or any person claiming through the Landlord.

27.20 Consent Not Unreasonably Withheld

Except as otherwise specifically provided, whenever any consent, approval, designation, requirement, opinion, judgment or discretion is required of either the Landlord or the Tenant under the terms of this Lease, the same shall be granted, determined, required or exercised reasonably and without delay unless otherwise stated.

27.21 Counterparts

This Agreement may be executed in several counterparts which shall together constitute the one and the same Agreement. It shall not be necessary in proving this Lease to produce or to prove more than one such executed counterpart.

28. ENVIRONMENTAL MATTERS

28.1 Definitions

For the purposes of this Article:

(a) "**Contaminants**" means any pollutants, contaminants, deleterious substances, underground or aboveground tanks, asbestos materials, urea formaldehyde, dangerous substances or goods, hazardous, corrosive or toxic substances, special waste or waste of any kind or any other substance which is now or hereafter prohibited, controlled or regulated under Environmental Laws; and

(b) "**Environmental Laws**" means any statutes, laws, regulations, orders, bylaws, standards, guidelines, permits and other lawful requirements of any governmental authority having jurisdiction over the Premises or the Building now or hereafter in force relating in any way to the environment, environmental assessment, health, occupational health and safety, product liability or transportation of dangerous goods, including the principles of common law and equity.

28.2 Compliance

Each of the Landlord and the Tenant will comply promptly with all lawful requirements of any Government Authority with which it must comply in order to observe or perform its obligations under this Lease, including all Environmental Laws.

28.3 Tenant's Covenants and Indemnity

The Tenant covenants and agrees as follows:

(a) not to use or permit to be used all or any part of the Premises for the sale, storage, manufacture, disposal, handling, treatment, use or any other dealing with any Contaminants, without the prior written consent of the Landlord, which may be unreasonably withheld. Without limiting the generality of the foregoing, the Tenant shall in no event use, and does not plan or intend to use, the Premises to dispose of, handle, treat or release any Contaminants in a manner that, in whole or in part, would cause the Premises, the Building or any adjacent property to become a contaminated site under Environmental Laws;

(b) to strictly comply, and cause any person for whom it is in law responsible to comply, with all Environmental Laws regarding the use and occupancy of the Premises;

(c) to promptly provide to the Landlord a copy of any environmental site investigation, assessment, audit, report or test results relating to the Premises or the Building conducted by or for the Tenant at any time before, during or after the Term (or any renewal thereof). The Tenant shall, at its own cost at the Landlord's request from time to time, obtain from an independent environmental consultant approved by the Landlord an environmental site investigation of the Premises or an environmental audit of the operations at the Premises, the scope of which shall be satisfactory to the Landlord and shall include any additional investigations that the environmental consultant may recommend. The Tenant shall promptly provide such written authorizations as the Landlord may require from time to time to make inquiries of any governmental authority regarding the Tenant;

(d) to waive the requirement, if any, for the Landlord to provide a site profile for the Premises under the *Environmental Management Act* and any regulations pursuant thereto;

(e) to maintain all environmental site investigations, assessments, audits, reports and test results relating to the Premises or the Building in strict confidence and not to disclose their terms or existence to any third party (including without limitation, any governmental authority) except as required by law, to the Tenant's professional advisers and lenders on a need to know basis or with the prior written consent of the Landlord, which consent may be unreasonably withheld;

(f) to promptly notify the Landlord in writing of any release of a Contaminant or any other occurrence or condition at the Premises, the Building or any adjacent property which could contaminate the Premises, the Building or subject the Landlord or the Tenant to any fines, penalties, orders, investigations or proceedings under Environmental Laws;

(g) prior to the expiry or earlier termination of this Lease or at any time if requested by the Landlord or required by any governmental authority pursuant to Environmental Laws, to remove from the Premises all Contaminants, and to remediate by removal any contamination of the Premises, the Building or any adjacent property resulting from

Contaminants, in either case brought onto, used at or released from the Premises by the Tenant or any person for whom it is in law responsible. The Tenant shall perform these obligations promptly at its own cost and in accordance with Environmental Laws. The Tenant shall provide to the Landlord full information with respect to any remedial work performed pursuant to this section and shall comply with the Landlord's requirements with respect to such work. The Tenant shall use a qualified environmental consultant approved by the Landlord to perform the remediation. The Tenant shall, at its own cost, obtain such approvals and certificates from the B.C. Ministry of Environment, and any other applicable regulatory authority in respect of the remediation as are required under Environmental Laws or required by the Landlord, including without limitation a certificate of compliance evidencing completion of the remediation satisfactory to the Ministry. All such Contaminants shall remain the property of the Tenant, notwithstanding any rule of law or other provision of this Lease to the contrary and notwithstanding the degree of their affixation to the Premises or the Building; and

(h) to indemnify the Landlord and its directors, officers, shareholders, employees, agents, successors and assigns, from any and all liabilities, actions, damages, claims, remediation cost recovery claims, losses, costs, orders, fines, penalties and expenses whatsoever (including all consulting and legal fees and expenses on a solicitor-client basis and the cost of remediation of the Premises, the Building and any adjacent property) arising from or in connection with:

(i) any breach of or non-compliance with the provisions of this Article by the Tenant; or

(ii) any release or alleged release of any Contaminants at or from the Premises related to or as a result of the use and occupation of the Premises by, or any act or omission of, the Tenant or any person for whom it is in law responsible.

The obligations of the Tenant under this Article shall survive the expiry or earlier termination of this Lease. The obligations of the Tenant under this Article are in addition to, and shall not limit, the obligations of the Tenant contained in other provisions of this Lease.

28.4 Landlord's Environmental Covenants

The Landlord covenants and agrees as follows:

(a) that it has not received any clean-up orders and is not aware of any violations of Environmental Laws, unremedied spills of Contaminants or storage of asbestos by the Landlord or by any prior occupant of the Premises;

(b) that it will comply throughout the Term with all applicable Environmental Laws and will not bring on to or release or discharge from the demised premises any Contaminants except in compliance with such laws; and

(c) that it will promptly remove from the Premises, in accordance with applicable Environmental Laws, any and all Contaminants introduced to the Premises by the Landlord and to promptly remediate any contamination of the Premises or other property caused by such Contaminants.

IN WITNESS WHEREOF, the Landlord and the Tenant have executed this Lease.

0846869 B.C. Ltd.
Landlord

Per:/s/ Gary Segal
Authorized Signatory

Per:
Authorized Signatory

ACHIEVE LIFE SCIENCES TECHNOLOGIES INC.
Tenant

Per:/s/ Jaime Xinos
Authorized Signatory

Per:
Authorized Signatory

SCHEDULE "A"

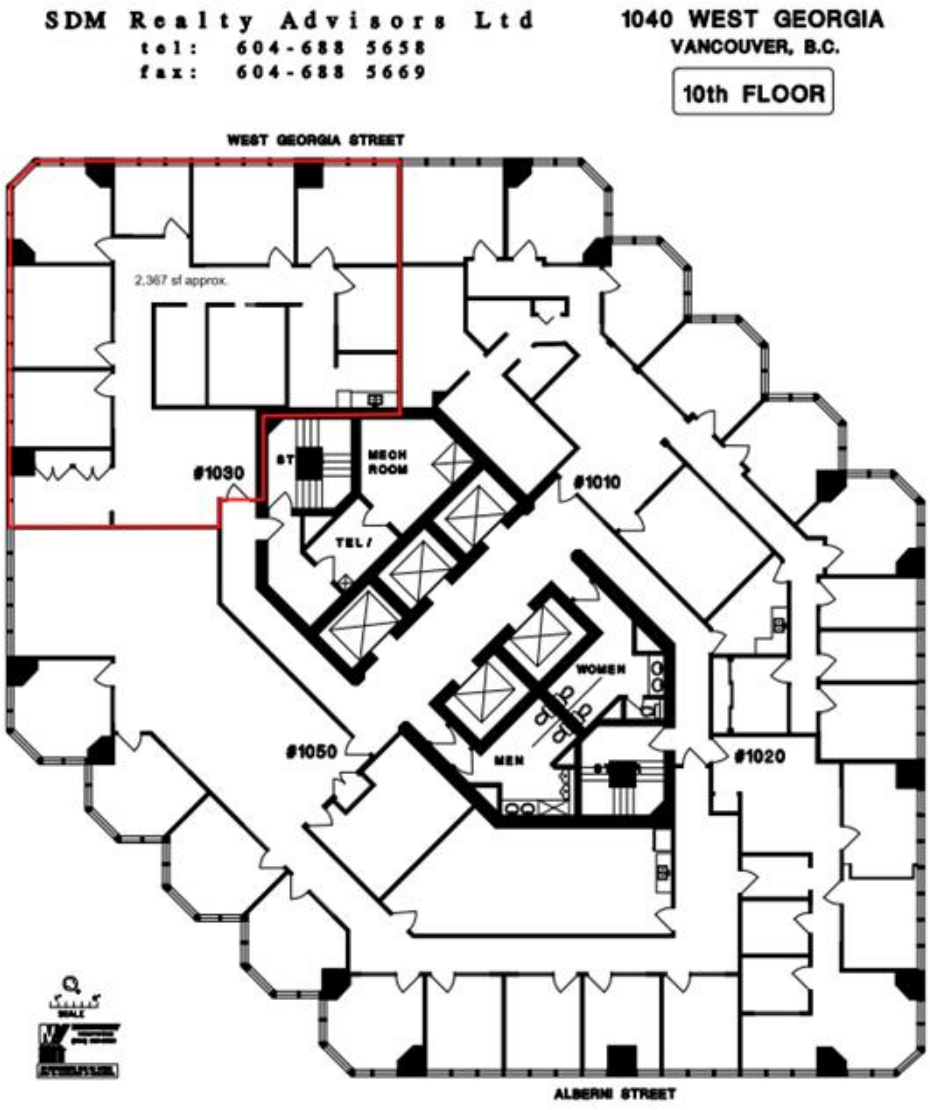
LEGAL DESCRIPTION

The "Building" when referred to in this Lease shall mean the Building, including parking structure and plaza, currently known as The Grosvenor Building situate at 1040 West Georgia Street, Vancouver, British Columbia including without limitation parking facilities, plazas, landscaping and ornamentation, plant, fixtures, machinery and equipment relating thereto and the lands upon which the foregoing are constructed or installed and any structures, equipment or facilities on, over or under adjacent streets and lanes constructed or installed by or for the Landlord in connection with the building and situate on those Lands more particularly described as:

Lot 5, 6 and 7
Block 4
District Lot 185
Plan 92
New Westminster District

PREMISES FLOOR PLAN

(Premises are shown outlined in red)



SCHEDULE "B"

RULES AND REGULATIONS

1. Use

(a) The sidewalks, plaza, entrances, lobbies, corridors, courts, elevators, escalators, vestibules or stairways in and about the Building shall not be obstructed or encumbered by any tenant or used for any purpose other than ingress or egress from the Premises.

(b) No tenant, employee or invitee of any tenant shall go up on the roof of the Building except such roof or part thereof as may be contiguous to the Premises of a particular tenant and is designated in writing by the Landlord as a roof-deck or roof-garden area.

(c) No cooking shall be done or permitted in the Building except the use by the Tenant of CSA approved equipment for brewing coffee, tea, hot chocolate and similar beverages and the use of CSA approved microwave ovens for heating (but not cooking foods) shall be permitted, provided that such use is in accordance with all applicable federal, provincial and city laws, codes, ordinances, rules and regulations and provided that such use shall not result in any odours emanating from the tenant's premises. Vending machines may be installed for the sale of foods and beverages to staff employed in the Building.

(d) No tenant shall use its premises in the Building for lodging or sleeping or for manufacturing, the storage of merchandise of the sale of merchandise, goods or property of any kind at auction.

(e) Nothing shall be placed or stored on patio areas nor shall anything be kept there temporarily, except tables secured to the satisfaction of the Landlord, and chairs. Patio doors shall be kept shut at all times other than to allow ingress or egress.

(f) No tenant shall throw anything out of the doors, windows or skylights or down the passageways or permit that to be done.

(g) Business machines and other equipment shall be placed and maintained by the Tenant at the Tenant's expense in settings sufficient, in the Landlord's reasonable judgment, to absorb and prevent unreasonable vibration and prevent noise and annoyance.

(h) Windows and doors that reflect or admit light and air into the halls, passageways or other public places in the Building shall not be covered by any tenant.

(i) No parcels or other articles be placed on interior or exterior window sills.

(j) No fire exit doors will be obstructed

2. Housekeeping

(a) No tenant shall employ any person or persons other than the Landlord's janitor for the purpose of cleaning the Premises, unless otherwise agreed to by the Landlord in writing. Except with the written consent of the Landlord no person or persons other than those approved by the Landlord shall be permitted to enter the Building for the purpose of cleaning the same. No tenant shall cause any unnecessary labour by reason of carelessness or indifference in the preservation of good order and cleanliness. Janitor service shall not include shampooing or spot cleaning of carpets nor dry cleaning of draperies. The Landlord shall not be responsible for any loss of or damage to any tenant's property by the janitor, its employees or any other person performing janitorial services.

(b) The Tenant shall permit window cleaners to clean the windows of the Premises both during Ordinary Business Hours and at other times.

(c) The washrooms, toilets, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, and no foreign substance of any kind whatsoever shall be thrown therein.

3. Trash

(a) Each tenant shall store all its trash and garbage within its Premises unless an alternative location is specifically provided by the Landlord. No material shall be placed in the trash boxes or receptacles if such material is of such nature that it may not be disposed of in the ordinary and customary manner of removing and disposing of trash and garbage without being in violation of any law or ordinance governing such disposal. All debris relating to the Alterations shall be removed from the Premises and the Building by the Tenant or its

contractors. All garbage, construction debris and refuse shall be removed only in suitable containers and through entry ways and elevators provided for such purposes and at such times as the Landlord shall designate. The Tenant shall not allow any undue accumulation of any debris, garbage, trash or refuse in or outside the Premises. If the Tenant uses perishable articles or generates wet garbage, the Tenant shall provide refrigerated storage facilities acceptable to the Landlord.

4. Safety

(a) Tenants shall not do or permit anything to be done in the Building, or bring or keep anything therein which is in any way hazardous or obstruct or interfere with the rights of other tenants or in any way injure or annoy them or the Landlord, violate or act contrary to the requirements of the Landlord's insurers.

(b) The Tenant shall co-operate with the Landlord in the holding of fire drills and in practicing building evacuation procedures.

(c) The Tenant shall not keep in the Premises or in the Building any dangerous or explosive or corrosive materials or fluids or batteries or other goods containing dangerous, explosive or corrosive materials or fluids. The Tenant shall not use or keep in the Premises or the Building any flammable or combustible fluid or material other than limited quantities thereof reasonably necessary for the operation or maintenance of office equipment. The Tenant shall not, without the Landlord's prior written approval, use any method of heating or air-conditioning other than that supplied or approved by the Landlord.

5. Security

(a) The Tenant shall ensure that the doors of the Premises are closed and locked, that all water faucets, water apparatus and powered equipment are shut off before the Tenant or the Tenant's employees leave the Premises, so as to prevent waste or damage, and for any default or carelessness in this regard, the Tenant shall make good all injuries sustained by the Landlord or other tenants or occupants of the Building.

(b) Tenants shall keep the doors to the Building corridors closed and locked at all times when not in use, except that the main entrance door to the Premises may be kept open during Ordinary Business Hours.

(c) No additional locks or bolts of any kind shall be placed upon any of the doors or windows by any tenant, nor shall any changes be made in existing locks or the mechanism thereof. Lock cylinders and keys shall be changed by the Landlord at the Tenant's expense upon receipt of written request from the Tenant.

6. Keys and Access Cards

(a) On or before or promptly following the Commencement Date the Landlord will furnish to the Tenant, free of charge, two keys per lock on the exterior door or doors of the Premises and, if applicable, or after installation of a security access card system for the Building, access cards assigned on a square foot basis.

(b) The Tenant must, upon the termination of his tenancy, return to the Landlord all keys and/or access cards either furnished to, or otherwise procured by, such tenant, and in the event of the loss of any keys so furnished, the Tenant shall pay to the Landlord the cost of replacement keys.

(c) Building janitors and contract cleaners will be provided with a passkey to offices in the Building.

7. Business Hours etc.

(a) The Ordinary Business Hours of the Building shall be 8:00 A.M. to 6:00 P.M. on weekdays and 8:00 A.M. to 1:00 P.M. on Saturdays (exclusive of Building Holidays).

(b) The "Building Holidays" to be observed by the Building shall be all statutory holidays in the jurisdiction in which the Building is situate and any and all other days designated by the Landlord.

(c) After Ordinary Business Hours and on Sundays and Building Holidays the Building will be secured, and air-conditioning, lighting and other Building services will not be provided.

8. Access

(a) On Sundays, Holidays and outside Ordinary Business Hours on other days, access to the Premises without proper and acceptable identification may be refused. The Tenant shall provide the Landlord with a current security access list for all persons authorized access to the Premises after Ordinary Business Hours. All changes, deletions and additions to said security access list shall be the sole responsibility of the Tenant and shall be made in writing to the Landlord. The Tenant shall be responsible for all persons to whom he has issued keys and/or security access cards and shall be liable to the Landlord for all acts of such persons. A written request for additional cards is required from the Tenant to the Landlord. A deposit shall be paid by the Tenant for each security access card. Any lost or stolen cards shall be promptly reported in writing by the Tenant to the Landlord. The Tenant shall be charged a fee for lost, stolen or unaccounted security access cards.

9. Signs, Directory and Building Address

(a) The Landlord may prescribe a uniform pattern of identification signs for tenants to be placed on the outside of the entranceway leading into the Premises at the Tenant's expense and other than such identification signs, the Tenant shall not paint, display, exhibit, inscribe, place or affix any flag, sign, picture, advertisement, notice, letter or direction on the outside or inside of the Premises for exterior view without the prior written consent of the Landlord. Signs shall be manufactured and installed by persons approved by the Landlord, failing which the Landlord may remove same without liability, and may charge the expense incurred by such removal to the Tenant.

10. Building Directory

(a) The Landlord shall place the Tenant's name on the Directory in the lobby of the Building at the Tenant’s expense. The Tenant shall not have the right to have additional names placed on the Directory except at the Tenant's expense and with the Landlord's prior written consent.

(b) The Landlord shall designate the style, size and location of identification, and the Directory shall be located in an area designated by the Landlord in the main lobby. The Tenant shall reimburse the Landlord for the cost of any subsequent amendments that the Tenant may from time to time request, and that are approved by the Landlord.

11. Building Name

(a) The Tenant shall not refer to the Building by any name other than that designated from time to time by the Landlord nor use such name for any purpose other than that of the business address of the Tenant, provided that the Tenant may use the civic address of the Building instead of the name of the Building. The Landlord shall have the right, without liability to any tenant, to change the name and street address of the Building.

12. Freight

(a) The delivery or movement of any freight, furniture, safes or bulky matter of any description (collectively herein called "freight") must take place during the hours which the Landlord may reasonably determine from time to time and in the designated freight elevator if an elevator is to be used. The persons employed by the Tenant for such work must be reasonably acceptable to the Landlord and only hand trucks equipped with rubber tires and side guards may be used for moving freight in the Building. All freight entering or leaving the Building must be shipped through the loading area and the designated freight elevator. In no event shall freight be moved through the ground floor entrance or lobbies of the Building. No elevators shall be used for the movement of freight between the hours of 7:30 A.M. and 9:30 A.M., between the hours of 12:00 P.M. and 2:00 P.M. or between the hours of 4:00 P.M. and 6:00 P.M. on any day. The Landlord reserves the right to inspect all freight to be brought into the Building and to exclude from the Building all freight which violates any term of this Lease.

(b) All carrying in or out of unusually heavy or bulk freight must take place only during hours selected by the Landlord and then only with prior notice to and approval by the Landlord. No loads beyond the rated capacity of elevators shall be brought into the Building. The Landlord shall have the right to prescribe the location of heavy loads or objects and if considered necessary, the means to distribute the weight thereof (to no more than 75 pounds per square foot unless written approval is granted by the Landlord). All costs incurred by the Landlord with respect thereto will be charged to the Tenant. Any damage to the Building caused by the Tenant or its contractor, delivery or moving service will be repaired at the Tenant's expense.

13. Building Delivery System

(a) The Landlord reserves the right to establish a delivery system within the Building and to require that all deliveries to the Tenant be made to a central location within the Building for distribution to the Tenant by the Landlord. The Landlord may make reasonable charges for such service.

14. Maintenance Requests

(a) The maintenance requests will be attended to only if made to the Landlord at the office of the Building. Building employees will not perform any work or do anything outside of their regular duties, unless under special instructions from the office of the Landlord.

(b) No tenant shall mark, paint, drill into, or in any way deface any part of the Premises or the Building or paint the acoustic ceiling tile, suspension grid or light fixtures.

(c) No tenant shall install vinyl tile or sheet, hand tile, marble, wood parquet, carpet or similar floor covering so that it is directly affixed to the floor of the Premises without the Landlord's approval. No installation of communication or electrical equipment and no boring or cutting or stringing of wires, conduits and plumbing pipes shall be permitted except with the prior written consent of the Landlord, and in accordance with any directions given by the Landlord or its consultants.

(d) No curtains, draperies, blinds, shutters, shades, screens or other coverings, hangings or decorations shall be attached to, hung or placed in, or used in connection with any window of the Building without the prior written consent of the Landlord.

(e) No file, cabinets, boxes, containers or similar items shall be placed in, against or adjacent to any window of the Building so as to be visible from the outside of the Building.

(f) No tenant shall install any radio, microwave or television antenna, loud speaker or other device on the roof or patio or exterior walls of the Building. No awnings, showcases, air-conditioning units or other items shall be put in front of or affixed to any part of the windows and exterior of the Building nor placed in the corridors or vestibules.

(g) No tenant shall alter the standard building ceiling lighting or HVAC system or install any additional lighting or abnormal power consuming equipment without written approval of the Landlord.

(h) The Landlord desires to retain uniformity of appearance from the exterior of the Building as far as is possible. Therefore no re-arrangement or replacement of the ceiling system or lighting fixtures within ten (10) feet of the perimeter of the Building nor use of draperies or blinds on the exterior of the Building other than the Building standard will be allowed without the express written consent of the Landlord.

15. Canvassing

(a) Canvassing, soliciting, distribution of handbills and peddling in the Building is prohibited and each tenant shall co-operate to prevent the same.

16. Animals

(a) No animals or pets are allowed in the Building, plaza or premises at any time, except seeing-eye dogs.

17. Bicycles and Vehicles

(a) Bicycles and vehicles are to be parked or left or secured only in areas designated by the Landlord.

SCHEDULE "C"

SPECIAL TERMS AND CONDITIONS

The following additional provisions are hereby incorporated in this Lease:

1. OPTION TO EXTEND

Option Exercise

a) Provided:

(i) the Tenant is not then in material default under the Lease; and

(ii) the Tenant gives the Landlord not less than Six (6) months' and not more than Nine (9) months' written notice prior to the expiry of the initial Term, of the Tenant's intention to extend the initial Term;

Then the Tenant will have the right to extend the initial Term upon the expiry of the initial Term for one (1) further period of Four (4) years (the "Extended Term") upon the same terms and conditions as are set out in the Lease, except that:

iii) There will be no further right to extend the Term;

iv) Any free rent allowance, or fixturing period, or tenant improvement allowance or other tenant incentive or inducement of any kind whatsoever, or any requirement on the Landlord's part to do any landlord's work in connection with the Lease, shall not apply to the Extended Term; and

v) The annual Basic Rent payable by the Tenant during the Extended Term shall be as agreed upon between the parties prior to the day which is 60 days before the commencement of the Extended Term based on the prevailing fair market basic rent at the commencement of the Extended Term for similarly improved premises of similar size, quality, use and location in buildings of a similar size, quality and location in Vancouver or, failing such agreement by such date, then as determined by arbitration in accordance with subparagraph b) below. In no event shall the Basic Rent be less than the Basic Rent in the last year of the initial Term.

The monthly Basic Rent payable during the Extended Term until the Basic Rent for the Extended Term is determined will be 100% of the monthly Basic Rent which was payable in the last full month of the initial Term. Basic Rent shall be applied retroactively to the commencement of the Extended Term and any amount owing by either party to the other by virtue of this retroactive application shall be paid within 14 days of the determination of the Basic Rent for the Extended Term. In no event shall the Basic Rent be less than the Basic Rent in the last year of the Initial Term.

b) If the parties fail to agree upon the annual Basic Rent payable during the Extended Term by a date 60 days prior to the commencement date of the Extended Term, either party may by notice in writing to the other require that the annual Basic Rent payable in respect of the Extended Term be determined by arbitration on the basis set out in subparagraphs 1(a)(v) above, such arbitration to be carried out by one arbitrator under the Arbitration Act (British Columbia), and amendments thereto, or any like statute in effect from time to time, if the parties can agree on one arbitrator, or if the parties cannot so agree within 14 days after they have started to negotiate as to who the single arbitrator shall be, each shall select one arbitrator and the two so selected shall within 21 days of the appointment of both them select a third arbitrator. The decision of such arbitrator (or arbitrators) shall be final and binding upon the parties. The costs of such arbitration shall be borne equally by the parties (except that each shall bear the cost of any arbitrator selected solely by it). Except as otherwise provided for herein, the provisions of the said Arbitration Act shall apply. All arbitrators shall be persons then active in the Province of British Columbia, as accredited Real Estate Appraisers and each shall have not less than five years' experience as an appraiser in the area where the Premises are located.

c) If the Tenant fails to exercise its option to extend the Term in accordance with this section, then the Tenant's rights under this section will terminate and be null and void.

2. TENANT IMPROVEMENT ALLOWANCE

As an inducement to enter into this Lease and for the purpose of constructing the Tenant's Work, the Landlord agrees to provide to the Tenant an improvement allowance in the amount of $8.00 per square foot of the Leased Premises. The improvement allowance shall, in any event, not

exceed $18,936.00 plus GST (the “Tenant Improvement Allowance) and shall be paid to the Tenant within thirty (30) days of completion of all of the following:

(a) the Tenant has completed construction of the Leasehold Improvements in accordance with the plans and drawings approved by the Landlord;

(b) the Tenant has executed and delivered the Lease to the Landlord;

(c) the Tenant is not in breach of the Lease and has commenced operation of its business from the Leased Premises;

(d) the Tenant has provided the Landlord with a Statutory Declaration stating that all contractors in connection with the Tenant’s Work have been paid and attaching copies of paid invoices;

(e) the Tenant has provided the Landlord with evidence that all necessary the Tenant has provided the Landlord with evidence that all necessary lien periods have expired.

Notwithstanding the foregoing, payment of the Tenant Improvement Allowance shall be subject to a holdback of 10% in accordance with the *Builders Lien Act*. Such holdback will be paid to the Tenant after the expiry of the statutory holdback period and following receipt by the Landlord of a statutory declaration of the Tenant and its approved contractor as to the nonexistence of nay liens encumbering the Lands in any way related to the Tenant’s improvement work, a current land titles search of the Lands confirming that no such liens are registered against the Lands and satisfactory confirmation that no actions have been commenced to enforce any such lien against the holdback.

3. PARKING

The Landlord shall provide up to three (3) random stalls and one (1) reserved stall in the parking garage of the Building for the use of the Tenant during the Term and the Tenant, at the Landlord’s request, shall enter into the Landlord’s standard license agreement for the stalls, at the market rent charged by the Landlord which may change from time to time. Parking is subject to all applicable taxes. The location of individual reserved stalls may be relocated on 30 days’ notice by the Landlord at any time during the Term. The current cost for reserved stalls is $400.00 per month plus taxes and $285.00 per month for random stalls plus applicable taxes.

4. FIXTURING PERIOD

For the purpose of planning and constructing the Tenant’s improvement work, the Tenant shall be entitled to have access to the Premises Thirty (30) days prior to the Commencement Date. During this period, the Tenant shall be bound by all the provisions of the Lease except that the Tenant shall not be obligated to pay any rent during such period. During such period, the Tenant’s occupancy of the Premises may be in common with the Landlord, its contractors, sub-contractors and employees.

5. DIRECTORY

The Tenant shall be entitled to one (1) entry on the directory for the building in which the Premises are located. If space permits, all of the members of the Tenant’s professional staff shall be separately listed.

SCHEDULE "D"

MORTGAGE CLAUSE

IT IS HEREBY PROVIDED AND AGREED THAT:

BREACH OF CONDITIONS BY MORTGAGOR, OWNER OR OCCUPANT

1.This insurance and every documented renewal thereof - AS TO THE INTEREST OF THE MORTGAGEE ONLY THEREIN - is and shall be in force notwithstanding any act, neglect, omission or misrepresentation attributable to the mortgagor, owner or occupant of the property insured, including transfer of interest, any vacancy or non-occupancy, or the occupation of the property for purposes more hazardous than specified in the description of the risk;

PROVIDED ALWAYS that the Mortgagee shall notify forthwith the Insurer (if known) of any vacancy or non-occupancy extending beyond thirty (30) consecutive days, or of any transfer of interest or increased hazard THAT SHALL COME TO HIS KNOWLEDGE; and that every increase of hazard (not permitted by the policy) shall be paid for by the Mortgagee - on reasonable demand - from the date such hazard existed, according to the established scale of rates for the acceptance of such increased hazard, during the continuance of this insurance.

RIGHT OF SUBROGATION

2.Whenever the Insurer pays the Mortgagee any loss award under this policy and claims that - as to the Mortgagor or Owner - no liability therefor existed, it shall be legally subrogated to all rights of the Mortgagee against the Insured; but any subrogation shall be limited to the amount of such loss payment and shall be subordinate and subject to the basic right of the Mortgagee to recover the full amount of its mortgage equity in priority to the Insurer; or the Insurer may at its option pay the Mortgagee all amounts due or to become due under the mortgage or on the security thereof, and shall thereupon receive a full assignment and transfer of the mortgage together with all securities held as collateral to the mortgage debt.

OTHER INSURANCE

3.If there be other valid and collectible insurance upon the property with loss payable to the Mortgagee - at law or in equity - then any amount payable thereunder shall be taken into account in determining the amount payable to the Mortgagee.

WHO MAY GIVE PROOF OF LOSS

4.In the absence of the Insured, or the inability, refusal or neglect of the Insured to give notice of loss or deliver the required Proof of Loss under the policy, then the Mortgagee may give the notice upon becoming aware of the loss and deliver as soon as practicable the Proof of Loss.

*TERMINATION

5.The term of this mortgage clause coincides with the term of the policy;

PROVIDED ALWAYS that the Insurer reserves the right to cancel the policy as provided by Statutory provision but agrees that the Insurer will neither terminate nor alter the policy to the prejudice of the Mortgagee without the notice stipulated in such Statutory provision.

§TERMINATION

6.The term of this mortgage clause coincides with the term of the policy;

PROVIDED ALWAYS that the Insurer reserves the right to cancel the policy as provided by statutory condition 19 as set forth in section 240 of the Insurance Act of Quebec, but agrees that the Insurer will neither terminate nor alter the policy to the prejudice of the Mortgagee without 15 days' notice to the Mortgagee by registered letter.

FORECLOSURE

7.Should title or ownership to said property become vested in the Mortgagee and/or assigns as owner or purchaser under foreclosure or otherwise, this insurance shall continue until expiry or cancellation for the benefit of the said Mortgagee and/or assigns.

SUBJECT TO THE TERMS OF THIS MORTGAGE CLAUSE (and these shall supersede any policy provisions in conflict therewith BUT ONLY AS TO THE INTEREST OF THE MORTGAGEE), loss under this policy is made payable to the Mortgagee.

* Termination Clause applicable to all Provinces except Quebec

§ Termination Clause applicable to the Province of Quebec

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 Statements on Form S-8 (File Nos. 333-56704, 333-135697, 333-144552, 333-153206, 333-168820, 333-190480, 333-197937, 333-206569, 333-221473, and 333-228253) and Form S-3 (File Nos. 333-184829, 333-207670 and 333-229019) of Achieve Life Sciences, Inc. of our report dated March 14, 2019 relating to the consolidated financial statements, which appears in this Form 10-K.

Vancouver, Canada,

March 14, 2019

/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 14, 2019

/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 14, 2019

/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, 2018 (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 14, 2019

/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, 2018 (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 14, 2019

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