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, 2023

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.)**

22722 29th Drive SE, Suite 100, Bothell, WA 98021

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

(604) 210-2217
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was $90,759,907 computed with reference to the price at which the Common Stock was last sold on June 30, 2023. As of March 28, 2024, 34,251,911 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement for its 2024 Annual Meeting of Stockholders ("Proxy Statement"), to be filed within 120 days of the Registrant's fiscal year ended December 31, 2023, is incorporated by reference into Part III of this Annual Report on Form 10-K.

Auditor Name: PricewaterhouseCoopers LLP Auditor Location: Vancouver, Canada Auditor Firm ID: 271

Achieve Life Sciences, Inc.

Table of Contents

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.

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:

- progress and preliminary and future results of any clinical trials;
- anticipated regulatory filings and U.S. Food and Drug Administration, or FDA, responses, recommendations, requirements or additional future clinical trials;
- our ability to raise additional capital as needed to fund our planned development and commercialization efforts and repay our existing debt;
- the potential benefits and differentiated profile, FDA approval, commercialization and commercial market for cytisinicline;
- the performance of, and our ability to obtain sufficient supply of cytisinicline in a timely manner from, third-party suppliers and manufacturers;
- timing and plans for the expansion of our focus to address other methods of nicotine addiction;
- timing and amount of future contractual payments, product revenue and operating expenses;
- market acceptance of our products and the estimated potential size of these markets; and
- our expectations regarding the impact of the macroeconomic and geopolitical environment, including inflation, rising interest rates, increased volatility in the debt and equity markets, instability in the global banking system, global health crises and pandemics and geopolitical conflict, and their potentially material adverse impact on our business and the execution of our preclinical studies and clinical trials.

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.

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled “Risk Factors” prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidates.
- We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be materially adversely affected if we are unable to service our debt obligations.
- 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 dependent upon a single company for the manufacture and supply of cytisinicline.

•We plan to submit an New Drug Application, or NDA, to the FDA for approval of cytisinicline as an aid in treating nicotine dependence for smoking cessation, based largely on data from our recently completed Phase 3 ORCA-2 and ORCA-3 clinical trials and planned ORCA-OL trial; however, there can be no assurance that the data from our clinical trials will ultimately support an NDA filing or that the FDA will grant marketing approval of cytisinicline without additional clinical or nonclinical studies, or at all.

•The development of our product candidate is dependent upon securing sufficient quantities of cytisinicline from trees and other plants, which grow outside of the United States in a limited number of locations.

•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.

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

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

•We currently exclusively rely on Sopharma to manufacture cytisinicline for use in clinical trials and plan to engage other third parties for our manufacturing process, including to manufacture cytisinicline on a commercial scale, 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 face substantial competition, and our competitors may discover, develop or commercialize products faster or more successfully than us.

•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.

ITEM 1. BUSINESS

OVERVIEW OF OUR BUSINESS AND RECENT DEVELOPMENTS

We are a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction. With more than one billion people who use tobacco globally and over 28 million adults who smoke in the United States alone, smoking remains the leading cause of preventable disease and death, responsible for more than eight million deaths annually worldwide. Our primary focus is to address this global epidemic.

We believe that cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. If approved by the U.S. Food and Drug Administration, or FDA, it stands to become the first new prescription medicine in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. We believe cytisinicline is differentiated from existing smoking cessation treatments given it has demonstrated in two randomized placebo controlled Phase 3 studies a combination of robust efficacy, minimal frequency of side effects and optional shorter course of therapy.

We plan to continue expanding our focus to address other methods of nicotine addiction such as e-cigarettes/vaping. The use of e-cigarettes continues to be widespread, with most recent reports from the Centers for Disease Control and Prevention indicating more than 11 million adult users in the United States alone in 2021. While e-cigarettes have been historically viewed as less harmful than combustible cigarettes, their long-term safety remains controversial. We believe that cytisinicline, if approved, could be the first prescription drug indicated for vape and e-cigarette users who are ready to quit their nicotine addiction.

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

Cytisinicline as our Product Candidate

Our product candidate, cytisinicline, is a naturally occurring, plant-based alkaloid. In 2018, the U.S. Adopted Names Council adopted cytisinicline as the non-proprietary, or generic, name for the substance also known as cytisine.

Cytisinicline is structurally similar to nicotine and has a well-defined, dual-acting mechanism of action that is both agonistic and antagonistic. It is believed to aid in smoking cessation and the treatment of nicotine addiction by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms through agonistic effects on nicotine receptors and by reducing the reward and satisfaction associated with nicotine through antagonistic properties.

Cytisinicline as a 25-day downward titration regimen is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by Sopharma AD, or Sopharma, for over 20 years. It is estimated that over 20 million people have used Sopharma's cytisinicline product to help treat nicotine addiction. We have developed an improved dosage and administration of cytisinicline that has demonstrated robust efficacy with minimal levels of adverse events in two randomized placebo controlled Phase 3 studies. We have an exclusive license and supply agreement with Sopharma for the development and commercialization of cytisinicline outside of Sopharma's territories which are predominately located in Central and Eastern Europe.

Cytisinicline Mechanism of Action

Cytisinicline is a partial agonist that binds with high affinity to the alpha-4 beta-2, or α4β2, nicotinic acetylcholine receptors in the brain. Through dual-acting partial agonist/partial antagonist activity, cytisinicline is believed to help reduce nicotine cravings, withdrawal symptoms and reward and satisfaction associated with smoking. The α4β2 nicotinic receptor is a well-understood target in addiction. When nicotine binds to this receptor, it causes dopamine to be released in the mid-brain, reinforcing the dopamine reward system. This receptor has been implicated in the development and maintenance of nicotine addiction. Cytisinicline is believed to act as a partial agonist at the α4β2 nicotinic receptor, preventing nicotine from binding and releasing dopamine.

Cytisinicline Opportunity

We have an exclusive license and supply agreement with Sopharma for the development and commercialization of cytisinicline outside of Sopharma's territory, which consists of certain countries in Central and Eastern Europe, Scandinavia, North Africa, the Middle East and Central Asia, as well as Vietnam. We intend to develop and commercialize cytisinicline in the United States, and

thereafter to target other markets outside of Sopharma's territory, such as Western Europe, Japan, China, Australasia, Southeast Asia and Latin and South America.

We are developing cytisinicline as an aid to smoking cessation and treatment for nicotine addiction to address the limitations of both prescription drugs and of Over-the-Counter, or OTC, products. We believe that a substantial market exists in the United States, European Union, or EU, and the rest of the world for a safe and effective smoking cessation treatment. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of robust efficacy, minimal frequency of side effects and optional shorter course of therapy, as shown in two randomized placebo controlled Phase 3 studies. Our goal is to obtain approval from the FDA and from other regulatory agencies for the sale and distribution of cytisinicline in the United States and subsequently to other countries outside of Sopharma's territory.

OVERVIEW OF OUR REGULATORY PROGRESS AND CLINICAL PHASE 3 PROGRAM

Overview of Regulatory Progress

Smoking Cessation Indication

In June 2017, we filed an Investigational New Drug Application, or IND, with the FDA, for evaluation of cytisinicline as a treatment for smoking cessation. This IND included required non-clinical toxicology studies that were sponsored by the National Center for Complementary and Integrative Health, or NCCIH, a division of the NIH and by the National Cancer Institute, or NCI, to assist in our IND for investigating cytisinicline as a smoking cessation treatment.

In May 2018, we held an end of Phase 2 meeting with the FDA to review and receive guidance on our Phase 3 clinical program and overall development plans to support an NDA for the 25-day downward titration cytisinicline regimen. The FDA recommended to consider evaluating higher dosing, a more simplified daily regimen, and possible longer dosing in our development program. This FDA review also included our plans and their recommendations for non-clinical studies, standard drug-to-drug interaction and reproductive/teratogenicity studies. Detailed plans for chronic toxicology, carcinogenicity studies, and additional clinical studies regarding a maximum tolerated dose, renal impairment, QT interval prolongation, longer term exposure and adequate demonstration of safety and efficacy from planned randomized, placebo-controlled, Phase 3 clinical trials were also discussed.

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

In November 2019, we held a type C meeting with the FDA to review results from our recently conducted Phase 2 ORCA-1 study and our revisions to the Phase 3 clinical program using a simplified 3 mg TID dosing schedule. The FDA agreed that the 3 mg TID dosing schedule was acceptable for our Phase 3 clinical program. In March 2019, we had also initiated our Phase 1 clinical study to assess for dose limiting adverse effects, or AEs, that would define the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. Because dose limiting AEs for the MTD could not reached in the study, the results were reviewed with the FDA at this November 2019 Type C meeting, with an agreement that further escalation beyond the single 30 mg dose was not required in the study.

Additional NCCIH and NCI sponsored non-clinical toxicology studies that evaluated reproductive toxicology and company sponsored non-clinical toxicology studies that evaluated longer cytisinicline treatment beyond one month to at least three months for support in initiating our Phase 3 clinical program were submitted in 2020. This allowed the initiation of our two Phase 3 clinical trials in the fourth quarter of 2020 and first quarter of 2022.

Additional plans for our Phase 1 studies regarding pharmacokinetics, or PK, assessments for subjects with renal impairment and evaluations for possible QT interval prolongation, which were first discussed with the FDA as part of the end of Phase 2 meeting in 2018, were followed by more detailed review and agreement with the FDA during 2022 and 2023. Both studies have now been completed.

During 2022 and 2023, we had several Type C and Type D meetings with the FDA regarding the adequacy of our completed nonclinical studies, overall clinical pharmacology information, manufacturing product information, and our Integrated Safety Summary, or ISS, analysis plans for a future NDA submission.

In the fourth quarter of 2023, we initiated our pre-NDA discussions with the FDA regarding the adequacy of our efficacy and safety information for proceeding with an NDA submission. The FDA expressed support for an NDA submission based on adequate data to

assess for efficacy from our two completed randomized and controlled Phase 3 trials. In addition, the FDA advised that long-term exposure data to assess for safety beyond 12 weeks would be needed to adequately assess safety risks given that the FDA views smoking cessation drugs as products for chronic, repeated, and intermittent use as patients may relapse and require subsequent courses of treatment over a lifetime. In the first quarter of 2024, we reached agreement with the FDA that a single, open-label study evaluating the long-term safety effects of cytisinicline will be sufficient to complete the requirement and enable an NDA submission anticipated in the first half of 2025.

E-cigarette (vaping) Cessation Indication

In July 2021, we announced that we were awarded a grant from the National Institute on Drug Abuse, or NIDA, of the National Institutes of Health, or NIH, to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. This initial grant award was utilized to complete critical regulatory activities for the submission of a second IND to the FDA for evaluation of cytisinicline as a treatment for nicotine e-cigarette cessation, or vaping cessation. In November 2021, we announced that the FDA had completed their review and accepted this IND to investigate cytisinicline in this population.

Based on the significant benefit from cytisinicline treatment for vaping cessation shown in our completed Phase 2 trial, we plan to request an end-of-Phase 2 meeting with FDA during 2024 to discuss a potential Phase 3 program for future supplemental NDA.

Non-Clinical Program Supportive of IND and Phase 3 Clinical Development

Non-clinical toxicology studies were sponsored by the NCCIH and by the NCI, to assist in our IND for investigating cytisinicline as a smoking cessation treatment. We filed this IND for cytisinicline with the FDA in 2017, which included the NCCIH sponsored non-clinical studies. Additional NCCIH and NCI sponsored non-clinical toxicology studies that evaluated reproductive toxicology were later submitted in support of our Phase 3 program.

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.

In addition, company sponsored non-clinical toxicology studies that evaluated longer cytisinicline treatment beyond one month to at least three months were submitted in 2020 prior to initiating our Phase 3 studies.

Non-clinical toxicology studies that are required for a New Drug Application, or NDA, including two longer-term chronic toxicology studies and two carcinogenicity studies, have been completed and submitted to the FDA.

Planned Company-Sponsored Clinical Trial

Planned Open Label ORCA-OL Trial

We plan to initiate an open label exposure trial, or ORCA-OL, in the second quarter of 2024 and expect to enroll subjects who previously received cytisinicline as part of the ORCA-program studies. ORCA-OL will recruit from the more than 1,700 subjects who have participated in these prior trials, including more than 1,100 who have already received cytisinicline treatment for either 6 or 12 weeks. Participants, whether they were previously using nicotine through smoking or vaping, will be encouraged to enroll in the study if they are currently using either, or both, forms of smoking and/or vaping nicotine. Subjects will receive cytisinicline treatment and be monitored for safety events for up to one year. The primary endpoint is frequency of serious adverse events. Other safety and efficacy outcomes will be assessed. The study is designed to enroll up to 650 subjects and is anticipated to start in the second quarter of 2024.

Based on agreement with FDA to follow ICH E1 guidance, the NDA submission will include data from a minimum of 300 subjects who have received cumulative cytisinicline treatment for six months, and prior to potential approval, we will provide the FDA with data from at least 100 subjects treated with cytisinicline for a cumulative duration of one year.

CLINICAL DEVELOPMENT PROGRAM

Company-Sponsored Completed Phase 1 Trials

Food Effect Phase 1 Trials

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

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

In 2023, we evaluated our planned commercial 3 mg formulated cytisinicline tablet in a 2-part Phase 1 clinical study with the first part evaluating the effect of food on the bioavailability of the 3 mg tablet in volunteer smokers. The study demonstrated similar bioavailability of cytisinicline in fed and fasted subjects and total excretion levels of cytisinicline also remained equivalent in both the fed and fasted states.

In all Phase 1 Food Effect studies, cytisinicline was well tolerated.

Other Phase 1 Safety Trials

In October 2017, we initiated a clinical study assessing the repeat-dose PK and pharmacodynamics, or PD, effects of 1.5 mg and 3 mg cytisinicline in 26 healthy volunteer smokers when administered over the 25-day downward titration regimen as marketed by Sopharma in their territories. Final results were presented at the Annual Meeting of the Society for Research on Nicotine and Tobacco, or SRNT, in February 2019. All 26 subjects completed the study. Predictable increases in plasma cytisinicline concentrations were observed with increasing unit dosing from 1.5 mg to 3 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 CO, and 46% of the subjects achieved biochemically verified smoking abstinence by day 26. Subjects who received 3 mg cytisinicline over the 25 days had a trend for higher smoking abstinence compared to subjects who received 1.5 mg cytisinicline. The AEs observed were mostly mild with transient headaches as the most commonly reported event. No serious adverse effects, or SAEs, were observed in the study.

In March 2019, we initiated a clinical trial to evaluate the dose limiting AEs that would define the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. This study evaluated smokers who received one single dose of cytisinicline. The starting dosage of cytisinicline was 6 mg and was to be increased in separate groups of subjects for each escalated dose level until stopping criteria (based on the occurrence of dose-limiting AEs) were reached. A safety review after each dose level was performed by an independent Data Safety Monitor Committee, or DSMC, before escalation to the next dose level. Six dose levels were pre-planned with 21 mg cytisinicline as the highest dose level. When the MTD was not reached at 21 mg, the study was amended to evaluate doses up to 30 mg, as recommended by the DSMC. At this 30 mg dose, the stopping criteria of serious or severe AEs were still not met, but the DSMC recommended stopping the study since the frequency of gastrointestinal symptoms were approaching an MTD level. The results were reviewed with the FDA, with an agreement that further escalation beyond the single 30 mg dose was not required. This Phase-1 study fulfills an FDA requirement to evaluate potential safety issues in the event patients exceed a recommended single dose outside of a clinical trial setting.

Three additional Phase 1 clinical studies were conducted in 2022 and 2023 for the NDA: one pharmacokinetics, or PK, study to evaluate for any increased cytisinicline blood levels in subjects who have various levels of renal impairment; another PK study to determine various remaining PK parameters for the 3 mg TID cytisinicline regimen, including the timing of steady state dosing; and a cardiac safety study to evaluate for any effects of cytisinicline on QT interval prolongation. All 3 studies have been completed.

The renal impairment study demonstrated that cytisinicline is excreted unchanged in urine and the pharmacokinetics of cytisinicline are dependent on renal function. Cytisinicline was generally observed to be well tolerated in subjects with varying degrees of renal impairment compared to subjects with normal renal function.

The PK study demonstrated that the 3mg cytisinicline TID dosing regimen reached steady state cytisinicline pharmacokinetics by the second day of TID administration.

The cardiac safety QT/QTc study evaluating therapeutic and supratherapeutic high doses of cytisinicline demonstrated that cytisinicline has no clinically relevant effect on QT interval prolongation or cardiac repolarization.

Company-Sponsored Completed Phase 2 Trials

Phase 2b ORCA-1 Trial for Smoking Cessation

We conducted the Phase 2b ORCA-1 dose selection trial, which was initiated in October 2018 and evaluated 254 smokers in the United States. The trial evaluated both 1.5 mg and 3 mg doses of cytisinicline on the standard declining titration schedule as well as a more simplified TID dosing schedule, both over 25 days. The trial was randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. All subjects were treated for 25 days, provided behavioral support, and followed up for an additional four weeks to assess smoking abstinence.

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

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

The secondary endpoint of the trial was a 4-week continuous abstinence rate, which is the relevant endpoint for regulatory approval. All cytisinicline treatment arms showed significant improvements in abstinence rates compared to the placebo arms. Notably, the 3 mg TID cytisinicline arm demonstrated a 50% abstinence rate at week 4, compared to 10% for placebo ($p<0.0001$) and a continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline compared to 8% for placebo ($p= 0.005$). Smokers in the 3 mg TID arm had an OR of 5.04 (95% CI: 1.42, 22.32) for continuous abstinence from week 5 to week 8, compared with placebo, meaning, smokers receiving 3 mg cytisinicline TID were five times more likely to stop smoking compared to smokers receiving placebo.

At week 4, all four cytisinicline arms demonstrated statistically significant ($p<0.05$) reductions in expired carbon monoxide, or CO, a biochemical measure of smoking activity. Expired CO levels had declined by a median of 71-80% in the cytisinicline treatment arms, compared to only 38% in the placebo arms.

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

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

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

Headache	6 (12%)	2 (4%)	1 (2%)	1 (2%)	10 (5%)	2 (4%)
Fatigue	3 (6%)	1 (2%)	1 (2%)	2 (4%)	7 (3%)	2 (4%)
Constipation	1 (2%)	3 (6%)	0 (0%)	0 (0%)	4 (2%)	1 (2%)

The outcome of the ORCA-1 trial was the selection of 3 mg TID for Phase 3 development. Overall, the 3 mg dose administered TID demonstrated the best overall safety and efficacy when compared to other doses and administrations studies in ORCA-1. The results from ORCA-1 study were published in the journal Nicotine and Tobacco Research in 2021.

Phase 2 ORCA-V1 Trial for E-cigarette (Vaping) Cessation

In June 2022, following NIDA/NIH review of completed regulatory and clinical operational milestones plus acceptance of the IND by FDA, we announced that we were awarded the next grant funding from NIDA in the amount of approximately $2.5 million. The full grant award of $2.8 million covered approximately half of the total ORCA-V1 clinical study costs. The Primary Investigators for the grant are our President and Chief Medical Officer, Dr. Cindy Jacobs, and Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director, Tobacco Research and Treatment Center, Massachusetts General Hospital.

In June 2022, we announced the initiation of the Phase 2 ORCA-V1 clinical trial. In April 2023, we reported positive topline results showing a statistically significant vaping cessation benefit for cytisinicline-treated participants in the ORCA-V1 trial.

ORCA-V1 evaluated 160 adults who used e-cigarettes on a daily basis at five clinical trial locations in the United States. ORCA-V1 participants were randomized to receive 3 mg cytisinicline three times daily or placebo for 12 weeks in combination with standard cessation behavioral support.

The primary endpoint for ORCA-V1 was biochemically verified continuous abstinence from nicotine e-cigarette use, measured during the last 4 weeks of treatment. Subjects who received 12 weeks of cytisinicline treatment had 2.6 times higher odds, or likelihood, to have quit vaping during the last four weeks of treatment compared to subjects who received placebo (p=0.035). The vaping cessation rate during weeks 9 through 12 was 31.8% for cytisinicline compared to 15.1% for placebo. A benefit in favor of cytisinicline was consistently observed across the secondary endpoints. Additionally, a cessation benefit was observed for cytisinicline across clinical trial sites and participant demographics such as age, gender, race, or whether they had smoked cigarettes in the past.

Cytisinicline was well tolerated and no SAEs were reported. Similar rates of AEs were observed between treatment arms (54.7% in the placebo arm vs. 50.9% in the cytisinicline arm). The most commonly reported (>5%) AEs in the placebo arm, in order of frequency, were nausea, COVID-19 infection, headache, anxiety, and upper respiratory tract infection. In the cytisinicline arm, >5% AEs reported, in order of frequency, were sleep disturbances, anxiety, headache, fatigue, and upper respiratory tract infection.

ORCA-V1 trial results were presented at the SRNT European annual meeting in September 2023 and the SRNT US annual meeting in March 2024.

Company-Sponsored Phase 3 Clinical Trials for Smoking Cessation Indication

Completed Phase 3 ORCA-2 Trial

In April 2022, we announced positive topline results for the Phase 3 ORCA-2 clinical trial. ORCA-2 was initiated in October 2020 and evaluated the efficacy and safety of 3 mg cytisinicline dosed three times daily compared to placebo in 810 adult smokers at 17 clinical sites in the United States. ORCA-2 participants were randomized to one of three study arms to determine the smoking cessation efficacy and safety profile of cytisinicline when administered for either 6 or 12 weeks, compared to placebo. All subjects received standard behavioral support and were assigned to one of the following groups:

- Arm A: 12 weeks of placebo
- Arm B: 6 weeks of cytisinicline, followed by 6 weeks of placebo

•Arm C: 12 weeks of cytisinicline

The ORCA-2 study had two independent primary endpoints that evaluated for successful smoking cessation for both 6-week and 12-week durations of cytisinicline treatment, compared to placebo. The primary endpoints for ORCA-2 were biochemically verified continuous smoking cessation measured during the last 4 weeks of each treatment duration. Both the 6- and 12-week cytisinicline treatments demonstrated significantly better quit rates than placebo with odds ratios, or ORs, of 8.0 and 6.3, respectively.

•Subjects who received 12 weeks of cytisinicline treatment had 6.3 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p<0.0001$). The abstinence rate during weeks 9-12 was 32.6% for cytisinicline compared to 7.0% for placebo.

•Subjects who received 6 weeks of cytisinicline treatment had 8.0 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p<0.0001$). The abstinence rate during weeks 3-6 was 25.3% for cytisinicline compared to 4.4% for placebo.

The secondary endpoints measured continuous smoking abstinence after treatment out to 24 weeks. Both the 6- and 12-week secondary endpoints for continuous abstinence demonstrated significantly better quit rates for cytisinicline treated subjects than placebo. The continuous abstinence rate from week 9 to 24 was 21.1% for the 12-week cytisinicline arm compared to 4.8% for placebo, with an OR of 5.3 ($p<0.0001$). The continuous abstinence rate from week 3 to 24 was 8.9% for the 6-week cytisinicline arm compared to 2.6% for placebo, with an OR of 3.7 ($p=0.0016$).

A third secondary endpoint compared the two cytisinicline treatment arms and evaluated for an increased risk in relapse from week 6 to week 24 when subjects were switched to placebo during week 6 to week 12 (Arm B) instead of receiving cytisinicline for another 6 weeks during week 6 to week 12 (Arm C). The analysis showed that there was no increased risk of smoking relapse in subjects who had successfully quit smoking by week 3 through week 6 if they received placebo instead of continuing cytisinicline from week 6 to week 12.

Cytisinicline was well tolerated with no treatment-related serious adverse events reported. The most commonly reported adverse events (occurring greater than 5% overall in the study) for placebo, 6-week cytisinicline, and 12-week cytisinicline, respectively, were:

	Placebo	6-Weeks Cytisinicline	12-Weeks Cytisinicline
Insomnia	4.8%	8.6%	9.6%
Abnormal Dreams	3.0%	8.2%	7.8%
Headaches	8.1%	6.7%	7.8%
Nausea	7.4%	5.9%	5.6%

Additional analyses from the ORCA-2 trial were presented at the Society for Research on Nicotine and Tobacco, or SRNT, annual meeting in March 2023 and final study results were published in the Journal of the American Medical Association, or JAMA, in July 2023.

Completed Phase 3 ORCA-3 Trial

In May 2023, we announced positive topline results for our Phase 3 ORCA-3 clinical trial. ORCA-3 was initiated in January 2022 and was a confirmatory Phase 3 trial required for registrational approval of cytisinicline in the United States and had the same design as the Phase 3 ORCA-2 trial. This Phase 3 trial evaluated the efficacy and safety of 3 mg cytisinicline dosed three times daily compared to placebo in 792 adult smokers at 20 clinical sites. ORCA-3 participants were randomized to one of three study arms to evaluate cytisinicline administered for either 6 or 12 weeks, compared to placebo. All subjects received standard behavioral support and were assigned to one of the following groups:

•Arm A: 12 weeks of placebo

•Arm B: 6 weeks of cytisinicline, followed by 6 weeks of placebo

•Arm C: 12 weeks of cytisinicline

The primary outcome measure of success in the ORCA-3 trial was biochemically verified continuous smoking cessation during the last four weeks of treatment in the 6 and 12-week cytisinicline treatment arms compared with placebo. Each treatment arm was compared independently to the placebo arm. Secondary outcome measures were conducted to assess continued smoking abstinence rates through six months from the start of study treatment.

Primary endpoint:

- Subjects who received 12 weeks of cytisinicline treatment had 4.4 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p<0.0001$). The smoking cessation rate during weeks 9 through 12 was 30.3% for cytisinicline compared to 9.4% for placebo.

- Subjects who received 6 weeks of cytisinicline treatment had 2.85 times higher odds, or likelihood, to have quit smoking during the last 4 weeks of treatment compared to subjects who received placebo ($p=0.0008$). The smoking cessation rate during weeks 3 through 6 was 14.8% for cytisinicline compared to 6% for placebo.

Secondary endpoint:

- The continuous smoking cessation rate from week 9 to week 24 was 20.5% for the 12-week cytisinicline arm compared to 4.2% for placebo, with an odds ratio of 5.79 ($p<0.0001$).

- The continuous smoking cessation rate from week 3 to week 24 was 6.8% for the 6-week cytisinicline arm compared to 1.1% for placebo, with an odds ratio of 6.25 ($p=0.0006$).

The third secondary endpoint compared the two cytisinicline treatment arms for an increased risk in relapse from week 6 to week 24 when subjects were switched to placebo during week 6 to week 12 (Arm B) instead of receiving cytisinicline for another 6 weeks during week 6 to week 12 (Arm C). The analysis showed that there was no increased risk of smoking relapse in subjects who had successfully quit smoking by week 3 through week 6 and switched to placebo.

ORCA-3 subjects had an average age of 53 years, smoked a median of 20 cigarettes per day at baseline, and had a median smoking history of 36 years with 4 prior quit attempts.

Similar to ORCA-2 findings, cytisinicline was well-tolerated with no treatment-related serious adverse events reported. The most commonly reported (>5% overall) adverse events for placebo, 6-week cytisinicline, and 12-week cytisinicline were:

	Placebo	6-Weeks Cytisinicline	12-Weeks Cytisinicline
Insomnia	7.6%	11.0%	11.9%
Abnormal Dreams	5.7%	9.1%	7.7%
Nausea	7.3%	9.5%	6.9%
Headaches	6.1%	7.6%	8.5%

Other Investigator-Sponsored Clinical Trials

In June 2020, we announced the topline results from the independent, investigator-sponsored Phase 3 RAUORA trial. RAUORA was a non-inferiority study comparing cytisinicline to Chantix (varenicline) in Māori (indigenous New Zealanders) and whānau (family) of Māori. The study was led by Dr. Natalie Walker, Associate Professor at the University of Auckland, and was funded by the Health Research Council of New Zealand. The study enrollment was planned for 2,140 subjects. In total, 1,105 Māori or whānau expressed interest in participating in the study and a total of 679 were randomized to receive either cytisinicline or varenicline. The average age of participants in the trial was 43 years and approximately 70% of the participants were women.

The study compared 1.5 mg tablets of cytisinicline administered on a schedule of 25 days of declining titration followed by twice-daily dosing for a total of 12 weeks with varenicline administered on a schedule of seven days of inclining titration followed by twice-daily dosing for a total of 12 weeks. The primary endpoint was a comparison of biochemically confirmed continuous abstinence rates at six months, and the trial was designed to assess if the two agents were non-inferior to each other.

The primary endpoint of the non-inferiority trial was to demonstrate that cytisinicline quit rates would be no less than 10% lower than the quit rates for varenicline. Topline results indicated that the RAUORA trial achieved its primary endpoint in showing that cytisinicline plus behavioral support was at least as effective as varenicline plus behavioral support at 6 months. Cytisinicline met the pre-specified non-inferiority endpoint and was trending towards superiority with an Absolute Risk Difference of +4.29 in favor of cytisinicline (95% CI -0.22 to 8.79), demonstrating a 4.29% improvement in quit rates in favor of cytisinicline. Specifically, continuous abstinence rates at 6 months, verified by expired CO, were 12.1% for cytisinicline compared to 7.9% for varenicline. The Relative Risk was 1.55 on an intent-to-treat basis, indicating that subjects in the cytisinicline arm were approximately one and a half times more likely to have quit smoking at 6 months compared to subjects who received varenicline.

Additionally, significantly fewer overall AEs were reported in cytisinicline-treated subjects (Relative Risk 0.56, 95% CI 0.49 to 0.65, $p<0.001$). Notably, of the subjects who experienced adverse events, cytisinicline subjects reported significantly less nausea, insomnia and vivid dreams ($p<0.05$).

The final RAUORA trial results and additional analyses were presented at the SRNT European Annual Meeting in September 2020 and were published in the journal Addiction in March 2021.

OVERVIEW OF SMOKING CESSATION MARKET AND TREATMENT OPTIONS

Overview of the Tobacco Epidemic

Smoking remains the leading cause of preventable death worldwide and in the United States. The World Health Organization, or WHO, estimates that there are approximately 1.3 billion tobacco users globally and that tobacco kills more than 8 million people each year. More than 7 million of those deaths are the result of direct tobacco use, while around 1.3 million are the result of non-smokers being exposed to second-hand smoke. In the United States alone, cigarette smoking is responsible for more than 480,000 deaths every year, or about one in five deaths.

The Centers for Disease Control and Prevention, or CDC, estimates that the annual cost of smoking related illnesses in the United States is more than $600 billion in direct medical care and lost productivity. Over 16 million people in the United States are living with a disease caused by smoking. Among these diseases are cancer, heart disease, stroke, lung diseases, diabetes and chronic obstructive pulmonary disease which includes emphysema and chronic bronchitis. Smoking also increases risk for tuberculosis, certain eye diseases and problems of the immune system, including rheumatoid arthritis. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke according to the CDC. Tobacco smoking is highly addictive, and research suggests that nicotine may be as addictive as heroin, cocaine and alcohol. The CDC estimates that more people in the United States are addicted to nicotine than any other drug and reports that, historically, nearly 70% of smokers desired to quit and 55% made an attempt to do so in the prior year. Despite the high number of attempts, fewer than one in ten people are successful in their attempt to quit each year. Additionally, up to 60% of people who quit smoking relapse in the first year.

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

According to data from the National Health Interview Survey, published by the CDC in May 2023, it is estimated that more than 11 million adults in the United States used e-cigarettes in 2021.

In a study that we conducted and that was presented at the 2021 SRNT Annual Meeting, surveying approximately 500 users of nicotine vaping devices or e-cigarettes, approximately 73% of participants responded that they intend to quit vaping within the next three to 12 months. Of those who intended to quit even sooner, within the next 3 months, more than half stated they would be extremely likely to try a new prescription product to help them do so. Further, survey data published in *JAMA Network Open* in 2021, found that 61% of adult vape users overall endorsed future plans to quit. Intentions to quit were highest, reported at 66%, in those survey participants who were former cigarette smokers and currently using vape devices.

We believe that cytisinicline, if approved, could be the first prescription drug indicated for vape and e-cigarette users who are ready to quit their nicotine addiction.

Overview of Smoking Cessation Marketplace & Treatments

According to DelveInsight's 2020 report "Smoking Cessation Market Insights, Epidemiology and Market Forecast", global revenues for prescription smoking cessation therapies are estimated to reach $5.6 billion by 2030. In 2023, approximately 8 million prescriptions were written for smoking cessation in the United States alone.

Only two non-nicotine, prescription treatments for smoking cessation are currently available in the United States: "varenicline" (formerly marketed by Pfizer as Chantix) and "bupropion" (formerly marketed by GlaxoSmithKline as Zyban). Both are currently available as generic formulations. Varenicline requires a three-month treatment period and bupropion is recommended for a period between seven and 12 weeks. While both have been proven effective in aiding smoking cessation, they are also associated with significant side effects and early discontinuations from treatment. Varenicline's labeling indicates elevated instances of nausea, abnormal dreams, constipation, flatulence, and vomiting may be experienced by varenicline-treated patients compared to placebo-treated patients, and buproprion's product label 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 varenicline's adverse event profile.

In June 2021, Pfizer Inc. halted the distribution of Chantix after heightened levels, above the FDA's acceptable daily intake limit, of nitrosamines were found in some lots of Chantix pills. In September 2021, Pfizer announced a nationwide recall in the United States of all lots of Chantix and have also withdrawn the product in other countries around the globe. Prior to market withdrawal and launch of generic Chantix (varenicline), global sales of branded Chantix peaked at $1.1 billion. Of those sales, approximately 75% were attributable to the U.S. market.

The vast majority of OTC smoking cessation aids are NRTs. NRTs come in many forms, including gums, lozenges and patches, and 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 with a number of NRTs and varenicline has been proven to be more effective than the NRTs, as demonstrated in head-to-head studies.

We believe that cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. If approved by the FDA, it stands to become the first new prescription medicine in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. With its product profile, cytisinicline is positioned to offer a novel solution characterized by robust efficacy and a lack of burdensome side effects in our clinical trials, which have hindered compliance and adoption with current treatments. Additionally, its dosing flexibility with a 6 or 12-week regimen, along with its natural derivation, is perceived favorably by certain potential patients.

LICENSE & SUPPLY AGREEMENTS

Sopharma

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

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

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

On July 28, 2017, we and Sopharma entered into the amended and restated Sopharma Supply Agreement. Pursuant to the amended and restated Sopharma Supply Agreement, for territories as detailed in the licensing agreement, we will exclusively purchase all of our

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

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma AD to acquire 75% of the outstanding shares of Extab Corporation for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the FDA or the European Medicines Agency, or EMA. The fair value of the contingent consideration on the acquisition date was nil. The contingent consideration liability is measured at fair value in our financial statements.

As of December 31, 2023, the fair value of the contingent consideration was estimated to be $0.5 million (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated Financial Statements). We recognized a loss of $0.5 million for the year ended December 31, 2023.

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, 2023, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

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

Summary of Milestone and Contingent Obligations by Product Candidate

The following table sets forth the milestones and contingent obligations that we may be required to pay to third parties under the license and share purchase 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)
Sopharma AD	$2,000,000(2)

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

(2)Payable contingent on regulatory approval by the FDA or EMA.

GOVERNMENT REGULATIONS

We are heavily regulated in most of the countries in which we operate. In the United States, the principal regulating authority is the FDA. The FDA regulates the safety and efficacy of product candidates and research, quality, manufacturing processes, product approval and promotion, advertising and product labeling. In the EU, the EMA and national regulatory agencies regulate the scientific evaluation, supervision and safety monitoring of product candidates, and oversee the procedures for approval of drugs for the EU and European Economic Area, or EEA, 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 and regulatory approval of cytisinicline in the United States. It is anticipated that cytisinicline tablets would receive a minimum five years of data exclusivity under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.

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

As a condition of product approval, the FDA may require a sponsor to conduct post-marketing clinical trials, known as Phase 4 trials, and surveillance programs to monitor the effect of the approved product. The FDA may limit further marketing of a product based on the results of these post-market trials and programs. Any modifications to a drug, including new indications or changes to labeling or manufacturing processes or facilities, may require the submission and approval of a new or supplemental NDA before the modification can be implemented, which may require that we generate additional data or conduct additional non-clinical studies and clinical trials. Our ongoing manufacture and distribution of drugs is subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences associated with the product, and adherence to current Good Manufacturing Practices, or cGMPs, which regulate all aspects of the manufacturing process. We are also subject to numerous regulatory requirements relating to the advertising and promotion of drugs, including, but not limited to, standards and regulations for direct-to-consumer advertising. Failure to comply with the applicable regulatory requirements governing the manufacture and marketing of our products may subject us to administrative or judicial sanctions, including warning letters, product recalls or seizures, injunctions, fines, civil penalties and/or criminal prosecution.

Sales and Marketing. The marketing practices of U.S. pharmaceutical companies are generally subject to various federal and state healthcare laws that are intended to prevent fraud and abuse in the healthcare industry and protect the integrity of government healthcare programs. These laws include anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a biopharmaceutical or medical device company from soliciting, offering, receiving or paying any remuneration to generate business, including the purchase or prescription of a particular product. False claims laws generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third-party payors (including Medicare and Medicaid) that are false or fraudulent. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to any particular industry practices, including the marketing practices of pharmaceutical and medical device companies. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions and/or exclusion from federal healthcare programs (including Medicare and Medicaid). The U.S. federal government and various states have also enacted laws to regulate the sales and marketing practices of pharmaceutical or

medical device companies. These laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require disclosure to the federal or state government and public of such interactions; and/or require the adoption of compliance standards or programs. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to penalties under the pertinent laws and regulations.

Healthcare Reform. The United States and state governments continue to propose and pass legislation designed to regulate the healthcare industry. In March 2020, the Patient Protection and Affordable Care Act, or ACA, as amended by the Healthcare and Education Reconciliation Act, or collectively, the Healthcare Reform Law, was passed and 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.

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

In the United States, Medicaid currently covers all smoking cessation products including varenicline and bupropion. The ACA substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Section 2502 of the ACA specifies that tobacco cessation medications will be removed from the list of optional medications and required for inclusion in states’ prescription drug benefit. On May 2, 2014 the Department of Health and Human Services, or HHS, provided guidance into insurance coverage policy that health plans would be in compliance if they cover, among other items, screening for tobacco use, individual, group and phone counseling, all FDA approved tobacco cessation medications (both prescription and OTC) when prescribed by a healthcare provider, at least two quit attempts per year, four sessions of counseling and 90 days of treatment, with no cost sharing (co-pay) required.

Government and private third-party payers routinely seek to manage utilization and control the costs of our products. For example, private third-party payers and the majority of states use preferred drug lists to restrict access to certain pharmaceutical products under both of these types of payer types. Private third-party payers are constantly under healthcare budgetary constraints and utilize Pharmacy Benefit Managers to extract unit cost savings from drug manufacturers for formulary coverage. 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.

There have also been multiple recent U.S. congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs and biologics. In addition, Congress and multiple presidential administrations have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or the IRA, in August 2022, which will, among other things, allows HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least seven years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023 and penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the

initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. We anticipate that additional state and federal healthcare measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for cytisinicline, or additional pricing pressures.

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 sought 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 included 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 introduced 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.

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

CONTRACT RESEARCH AGREEMENTS

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

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

MANUFACTURING

We do not own or operate manufacturing facilities for the production of cytisinicline, though we may develop our own manufacturing operations in the future. We currently partner with Sopharma as supplier and contract manufacturer for 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 and are in the process of contracting with additional contract manufacturing organizations for commercial drug supply. We currently employ internal resources and third-party consultants to manage our clinical manufacturing activities.

Sopharma sources cytisinicline from natural sources including trees and shrubs from the Faboideae subfamily of plant species. The seeds of cytisinicline containing plants are harvested annually, dried and processed into cytisinicline. The seeds in their natural state are highly toxic and the extraction process removes the toxins to produce highly purified cytisinicline. Sopharma controls a number of

orchards throughout Bulgaria in addition to sourcing seeds and cytisinicline starting material from certain third-party suppliers. We expect to continue stockpiling cytisinicline to meet the projected demand from us upon commercial launch.

The active pharmaceutical ingredient, or API, manufacturing process utilizes a series of techniques including solvent extraction, recrystallization, 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. During 2022, Sopharma built a new API facility specifically for cytisinicline within its tableting plant in Sofia.

Raw materials are essential to our business and are normally available in quantities adequate to meet the needs of our business. Where there are exceptions, the temporary unavailability of those raw materials has not historically had a material adverse effect on our financial results however, uncertainties in supply chain, transportation logistics and costs, and political and economic conditions could result in disruptions in our operations and materially impact our financial results.

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 marketing and sales infrastructure. We plan to further evaluate these alternatives including the potential to market and distribute directly to consumers via traditional and virtual channels. We intend to seek commercial partnerships in ex-U.S. territories.

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, therefore, the compound itself is not patentable in the United States. Furthermore, cytisinicline has been used in other parts of the world for decades, creating further challenges to patenting uses of the compound.

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

Additionally, we are actively building an intellectual property portfolio around our clinical-stage product candidate and research programs. A key component of this portfolio strategy is to seek international patent protection with patent applications in the United States and in major market countries that we consider important to the development of our business. As of December 31, 2023, we own a portfolio of four patent families. Those families cover cytisinicline derivatives (being prosecuted in the United States, Australia, Canada, China, Europe, U.K. and Japan), novel cytisinicline salts (being prosecuted in the United States, Australia, Canada, China, Europe, Hong Kong, South Korea, Japan and New Zealand with issued patents in the U.K., Canada, United States, Mexico and South Africa), and novel cytisinicline dosing methods being prosecuted in the United States, Brazil, Canada, China, Europe, Japan, South Korea, Mexico, and New Zealand, with issued patents in the United States. Additionally, we have in-licensed rights from Sopharma to two patent families relating to a new method of cytisinicline extraction, as well as cytisinicline formulations and one family from a third party relating to cytisine purity. As of December 31, 2023, we owned or in-licensed 26 issued patents and 50 pending patent applications. These patents have expirations dates ranging from 2037 to 2042, absent any term adjustments or extensions.

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 they may seek to develop or commercialize in the future. We are aware that many companies have therapeutics marketed or in development for smoking cessation. 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 and Over-the-Counter Treatments

Only two non-nicotine, prescription treatments for smoking cessation are currently available in the United States; “varenicline” (formerly marketed by Pfizer as Chantix) and “bupropion” (formerly marketed by GlaxoSmithKline as Zyban). Both are currently available as generic formulations. Varenicline requires a three-month treatment period and bupropion is recommended for a period between seven and 12 weeks. While both have been proven effective in aiding smoking cessation, they are also associated with significant side effects and early discontinuations from treatment. Varenicline’s labeling indicates elevated instances of nausea, abnormal dreams, constipation, flatulence, and vomiting may be experienced by varenicline-treated patients compared to placebo-treated patients, and bupropion’s product label discloses potential adverse reactions including insomnia, rhinitis, dry mouth, dizziness, nervous disturbance, anxiety, nausea, constipation, arthralgia and seizures. Both varenicline and buproprion have warning and precautions for neuropsychiatric adverse events, including suicidal ideations. High uptake into the brain combined with activity at “off target” receptors could be responsible for varenicline’s adverse event profile.

In June 2021, Pfizer Inc. halted the distribution of Chantix after heightened levels, above the FDA’s acceptable daily intake limit, of nitrosamines were found in some lots of Chantix pills. In September 2021, Pfizer announced a nationwide recall in the United States of all lots of Chantix and have also withdrawn the product in other countries around the globe. Prior to market withdrawal and launch of generic Chantix (varenicline), global sales of branded Chantix peaked at $1.1 billion. Of those sales, approximately 75% were attributable to the U.S. market.

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

Pharmaceutical companies, including larger companies in the industry, who have extensive expertise in non-clinical and clinical testing and in obtaining regulatory approvals for products, may develop other OTC treatments for smoking cessation. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

HUMAN CAPITAL RESOURCES

As of December 31, 2023, we had a total of 22 employees, of whom thirteen were engaged in research and development functions, including clinical development, regulatory affairs and manufacturing, and nine were engaged in general and administrative functions, including accounting and finance, administration, and commercial.

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.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We emphasize a number of measures and objectives in managing our human capital assets, including, among others, employee engagement, development, and training, talent acquisition and retention, employee safety and wellness, diversity and inclusion, and

compensation and pay equity. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off.

COMPANY INFORMATION

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

AVAILABLE INFORMATION

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider 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

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.

We have expended and continue to expend substantial funds in connection with our product development activities and clinical trials and regulatory approvals. 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, seek regulatory approval for, and commercialize, cytisinicline and add personnel necessary to operate as a commercial-stage public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs, efforts to achieve regulatory approval and prepare for commercialization.

Funds generated from our operations will be insufficient to enable us to bring all of our products currently under development to commercialization. We will continue to require substantial additional capital to continue our clinical development activities and expand our regulatory, manufacturing and commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to finance the remaining development and commercialization of our product candidate. The current financing environment in the United States, particularly for biotechnology companies like us, is challenging and we can provide no assurances as to when this will improve. Our business may be impacted by macroeconomic conditions, including inflation, interest rates and market conditions as well as political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control. These factors may make it challenging to raise additional capital on favorable terms, if at all. A severe or prolonged economic downturn could result in a variety of risks to our business, including in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. In addition, current macroeconomic conditions have caused turmoil in the banking sector. Further, the maturity date of our Convertible Term Loan could accelerate in certain circumstances related to the timing of our submission and the FDA's acceptance of a New Drug Application, or NDA. 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:

- the progress and results of our research and development programs;
- the repayment or conversion of our outstanding debt;
- our commercialization activities and arrangements;
- 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;
- the effect of interest rate adjustments, which may impact the cost of our borrowing under our loan facility, which includes an adjustable-rate component; and
- the terms of any new collaborative, licensing, commercialization and other arrangements that we may establish.

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

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be materially adversely affected if we are unable to service our debt obligations.

As of December 31, 2023, the principal amounts due under our debt instruments (including the Debt Agreement, as further described under the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”) totaled $17.3 million.

Servicing our debt requires a significant amount of cash. Our debt is subject to floating interest rates set in relation to the prime rate. Increases in interest rates have made and may continue to make our debt service costs increase. The Convertible Term Loan matures on December 22, 2024, but the Debt Agreement contains maturity acceleration clauses. In the event we fail to receive a Filing Communication that the FDA has accepted for filing our NDA with respect to cytisinicline for a smoking cessation indication, on or prior to July 31, 2024, the maturity date shall be August 1, 2024 or in the event we receive a Filing Communication with respect to cytisinicline for a smoking cessation indication on or prior to August 14, 2024, but where such Filing Communication specifies any material deficiencies or material filing review issues with respect to such NDA, the maturity date shall be August 15, 2024; provided, further, that in the event we have submitted the NDA on or prior to June 30, 2024, each of the maturity dates listed above shall be extended by one calendar month. In light of our recent discussions with the FDA and our current plans for the submission of an NDA for cytisinicline, if we are unable to secure a waiver or renegotiate the terms of the Debt Agreement, we expect that the Convertible Term Loan will mature on August 1, 2024. If we are at any time unable to service our indebtedness, we may be required to attempt to renegotiate the terms of the loan, seek to refinance all or a portion of the loan or seek additional financing. We and the Lenders have entered into a non-binding Term Sheet for an extension of the maturity date for the Convertible Term Loan, but there is no guarantee that we will be able to enter into a definitive agreement with the Lenders on these terms or any at all. We currently do not generate any cash flow from operations and if we are unable to make interest and/or principal payments when due, we would be in default under the Debt Agreement. We may be required to raise additional capital through future financings or sales of assets to enable us to make interest payments and/or repay our outstanding indebtedness as it becomes due. There can be no assurance that we will be able to generate cash or raise additional capital. Any debt financing that is available could cause us to incur substantial costs and subject us to covenants that significantly restrict our ability to conduct our business. If we seek to complete additional equity financings, the interests of existing stockholders may be diluted. If we are unable to service our loan, the lender may foreclose on and sell the assets securing such indebtedness to satisfy our payment obligations, which could prevent us from accessing those assets for our business and conducting our business as planned, which could materially harm our financial condition and results of operations.

Our obligations under the Debt Agreement are secured by substantially all of our assets, other than intellectual property. If we are unable to make payment on our secured debt instruments when due, the lender under such instrument may foreclose on and sell the assets securing such indebtedness to satisfy our payment obligations, which could prevent us from accessing those assets for our business and conducting our business as planned, which could materially harm our financial condition and results of operations.

Further, if we are liquidated, the rights of the Lenders to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lenders could declare a default under the Debt Agreement upon the occurrence of any event that the Lenders interpret as a material adverse change as defined under the Debt Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the Lenders of an event of default could significantly harm our business, financial condition, results of operations and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Further, the Debt Agreement contains customary affirmative and restrictive covenants, including covenants regarding the incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, mergers or acquisitions, and the requirement we keep substantially all of our cash and investments with SVB, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on capital stock, subject to limited exceptions. The Loan Agreement includes customary representations and warranties, events of default and termination provisions.

Our existing and any future indebtedness may limit our cash resources available to invest in the ongoing needs of our business.

Our outstanding debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- reducing cash resources available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and funds from external sources. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing or any future debt facility. Funds from external sources may not be available on acceptable terms, if at all.

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 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 expect to continue incurring losses for the foreseeable 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 developing our cytisinicline product candidate and supporting our operations. To date, we have funded the company primarily through the sale of equity securities and convertible promissory notes.

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 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;
- experience delays in the development of our cytisinicline candidate, including delays in clinical trials;
- encounter safety concerns; or
- require additional studies to support regulatory approval and commercialization.

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

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

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory 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 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 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 or alternative products, including the potential for generic cytisinicline products;
- protecting and enforcing our intellectual property rights, if any, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, commercialization, or other arrangements into which we may enter; and
- attracting, hiring, and retaining qualified personnel.

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

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions, including with Silicon Valley Bank, or SVB, both in the United States and internationally, in excess of the FDIC insurance limit and similar regulatory insurance limits outside the United States. Further, if we enter into a credit, loan or other similar facility with a financial institution, certain covenants included in such facility may require as security that we keep a significant portion of our cash with the institution providing such facility. If a depository institution where we maintain deposits fails or is subject to adverse conditions in the financial or credit markets, we may not be able to recover all, if any, of our deposits which could adversely impact our operating liquidity and financial performance.

Under the terms of the Debt Agreement, we are required to keep substantially all of our cash and investments with SVB. In March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which also appointed the FDIC as receiver. Within days, the FDIC assisted depositors of the bank access funds and we were able to regain full access to our cash and cash equivalents with SVB. In May 2023, First Citizens assumed all of SVB's deposits and loans. While our deposits are backed by the FDIC, that support may not last or be honored in the future and we could be materially impacted.

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 cytisinicline and it cannot be marketed or sold in the United States or in foreign markets until regulatory approval has been obtained from the FDA or applicable foreign regulatory agencies. The process of obtaining regulatory approval is expensive and time consuming. The FDA and foreign regulatory authorities may never approve cytisinicline for sale and marketing, and even if cytisinicline is ultimately approved, regulatory approval may be delayed or limited in the United States or in other jurisdictions. Even if we are authorized to sell and market cytisinicline in one or more markets, there can be 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.

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, Sopharma. We are required to continue to contract with Sopharma, to continue our development of, and potential commercialization of, cytisinicline pursuant to a supply agreement with Sopharma. Sopharma currently manufactures all of its cytisinicline API in its facilities in Bulgaria. The conflict in Ukraine, including the possibility of expanded regional or global conflict and related economic sanctions, may have negative impacts on Sopharma's business, which could cause them to reduce or terminate investments in the cytisinicline program. If the supply agreement with Sopharma is terminated, we will need to secure alternative supply and manufacturing capabilities for cytisinicline, which we may not be able to do on commercially viable terms or at all and would likely delay development, regulatory approval and commercialization.

We plan to submit an NDA to the FDA for approval of cytisinicline as an aid in treating nicotine dependence for smoking cessation, based largely on data from our recently completed Phase 3 ORCA-2 and ORCA-3 clinical trials and planned ORCA-OL trial; however, there can be no assurance that the data from our clinical trials will ultimately support an NDA filing or that the FDA will grant marketing approval of cytisinicline without additional clinical or nonclinical studies, or at all.

Drug product candidates must demonstrate substantial evidence of effectiveness, as well as safety to be approved in the United States. The FDA has interpreted that statutory standard as generally requiring at least two adequate and well-controlled clinical trials, each convincing on its own, to establish effectiveness and a safety profile. Under certain circumstances the FDA will determine that data from one adequate and well-controlled clinical trial together with confirmatory evidence obtained prior to or after such clinical trial are sufficient to constitute substantial evidence of effectiveness.

Cytisinicline is a naturally occurring, plant-based alkaloid. Cytisinicline is structurally similar to nicotine and has a well-defined, dual-acting mechanism of action that is both agonistic and antagonistic. It is believed to aid in smoking cessation and the treatment of nicotine addiction by interacting with nicotine receptors in the brain, reducing the severity of nicotine withdrawal symptoms through agonistic effects on nicotine receptors and reducing the reward and satisfaction associated with nicotine through antagonistic properties. Cytisinicline has been studied in two company-sponsored randomized, multicenter, double-blind, placebo controlled Phase 3 clinical studies that randomized a total of 1,602 adult smokers in 37 study sites across the United States.

The FDA has advised us that long-term exposure data to assess for safety beyond 12 weeks will be needed to adequately assess safety risks given that the FDA views smoking cessation drugs as products for chronic, repeated, and intermittent use as patients may relapse and require subsequent courses of treatment over a lifetime. In the first quarter of 2024, we reached agreement with the FDA that a single, open-label study, which we refer to as ORCA-OL, evaluating the long-term safety effects of cytisinicline will be sufficient to complete the requirement and enable an NDA submission. However, regardless of these discussions and the results of the ORCA-OL open label study, the FDA may determine that:

•the existing data, and the data from the ORCA-OL open label study, may not be sufficient and the FDA may require additional clinical and/or nonclinical studies prior to filing an NDA and approval of cytisinicline for treating nicotine dependence for smoking cessation in adults;

•the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

•the product candidate's risk-benefit ratios for the proposed indication may not be acceptable;

•the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an application for marketing authorization; and

•third-parties' manufacturing processes or facilities with which we contract for clinical and commercial supplies may not meet the standards required for approval.

Failure to obtain regulatory approval to market our product candidate would significantly harm our business, results of operations, and prospects.

The development of our product candidate is dependent upon securing sufficient quantities of cytisinicline from trees and other plants, which grow 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 trees and shrubs from the Faboideae subfamily of plant species, which grow in the mountains of Southern Europe and other limited locations around the world. We have and will continue to pursue alternative sources for cytisinicline, including synthetic routes, however, all of the cytisinicline sourced to date for our product candidate has been from natural sources and there is no guarantee that any potential synthetic route developed will be commercially viable. 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 trees and shrubs from the Faboideae subfamily of plant species will continue to grow in sufficient quantities around the world to meet our forecasts or commercial supply requirements or that the countries from which we can secure them will continue to allow the exportation of cytisinicline. Additionally, economic or political instability or disruptions, such as the conflict in Ukraine, could negatively affect our supply chain or increase our costs. If these types of events or disruptions continue to occur, they could have a material adverse effect on our business, financial condition, results of operations and cash flows. 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.

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, including the planned ORCA-OL trial, are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. Any advances of cytisinicline into clinical trials may not have favorable results or receive regulatory approval.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trial, including the planned ORCA-OL trial, will be conducted as planned or completed on schedule, if at all. Events that may prevent successful or timely completion of the planned ORCA-OL trial, but are not limited to:

•delays in recruiting qualified subjects who previously participated in the ORCA-program studies;

•subjects terminating enrollment in the ORCA-OL trial;

•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;

•disruptions to our supply chain for the cytisinicline required for the ORCA-OL trial;

•the occurrence of previously unknown on unobserved adverse events or tolerability issues associated with our product candidate, including those significant enough to stop the trial or for the FDA or other regulatory agencies to put the ORCA-OL trial on hold;

•the cost of the ORCA-OL trial;

•negative or inconclusive results from the ORCA-OL trial, which may result in us deciding, or regulators requiring us, to conduct further additional clinical trials or abandon development programs in ongoing or other planned indications for cytisinicline;

•discovery of impurities in our cytisinicline drug product, such as nitrosamines, above the regulators' prescribed thresholds; and

•delays in the manufacture or packaging of sufficient quantities of cytisinicline for use the ORCA-OL trial.

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 result in delayed regulatory approval and potential commercialization, as well as 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.

Further, even if the ORCA-OL trial is completed as planned, we cannot be certain that its long-term safety results will be consistent with the results of the earlier clinical trials of cytisinicline or support an NDA filing. Positive results in non-clinical testing and past clinical trials with respect to the adequate safety and efficacy of cytisinicline do not ensure that results from subsequent clinical trials will also be positive or adequate, 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 conduct our business and generate any product revenues and result in a loss of company value.

Cytisinicline may cause undesirable side effects or have other properties that could delay or prevent 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. Even if approved, these could result in a restrictive label, a shelf life that is not commercially viable or delay regulatory approval by the FDA or comparable foreign authorities.

If contaminants, or impurities such as nitrosamines, are discovered in quantities above regulators' thresholds within our supply of cytisinicline, we may potentially delay product development and approval or have a material adverse impact on our business. Failure to reach agreement with the FDA on acceptable intake levels for impurities, such as nitrosamines, or exceeding agreed upon levels could delay or prevent regulatory approval.

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 subject to product liability claims 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 any and all 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 and reputation.

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

Where we have provided indemnities in favor of third parties under our agreements with them, there is a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may also bring a product liability claim against us alleging that cytisinicline causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts.

Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- an inability to commercialize, or if commercialized, a decreased demand for, cytisinicline;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenue, if any;
- substantial costs of litigation, including monetary awards to patients or other claimants;

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- increased product liability insurance rates, or inability to maintain insurance coverage in the future on acceptable terms, if at all;
- diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

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

Our business may be negatively affected by weather conditions, natural disasters, 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 Faboideae subfamily of plant species 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 in the locations where cytisinicline is sourced. The long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify existing risk of natural disasters. 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 conduct clinical trials internationally, which may trigger additional risks.

Conducting clinical trials in Europe or other countries outside of the United States has additional regulatory requirements that we 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. For example, we have recently conducted clinical trials in Spain and Portugal and are subject to the local regulatory requirements of such jurisdictions.

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.

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

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

We will need approval from the FDA to commercialize cytisinicline in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize cytisinicline in those jurisdictions. In order to obtain FDA approval of cytisinicline, we must submit an NDA to the FDA, demonstrating that cytisinicline is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate and

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

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

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

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

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

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

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;

- •suspend any of our ongoing clinical trials;
- •refuse to approve pending applications or supplements to approved applications submitted by us;
- •impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- •require a product recall.

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

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

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

- •the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- •federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- •the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- •HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- •the federal physician sunshine requirements under the Healthcare Reform Law requires manufacturers of products, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- •state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Healthcare Reform Law was passed, which substantially changed 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.

There have also been multiple recent U.S. congressional inquiries and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs and biologics. In addition, Congress and multiple presidential administrations have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or the IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in U.S. Affordable Care Act, or ACA, marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. We anticipate that additional state and federal healthcare measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for cytisinicline, or additional pricing pressures. Currently, ACA and other federal laws and rules require most health insurance plans in the U.S. to cover some level of tobacco cessation treatments, including smoking cessation counseling and medications. If these provisions are repealed, in whole or in part, our business, financial condition, or results of operations could be negatively affected.

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 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.

In July 2021, we announced that we were awarded a grant from NIDA to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. This initial grant award, in the amount of $320,000, commenced on August 1, 2021, and was utilized to

complete critical regulatory and clinical operational activities, such as protocol finalization, clinical trial site identification, and submission of an IND to the FDA for investigating cytisinicline in nicotine e-cigarette users. In November 2021, we announced that the FDA had completed their review and accepted the IND to investigate cytisinicline as a cessation treatment in this population. In June 2022, following NIDA/NIH review of completed milestones, we announced that we were awarded the next grant funding from NIDA in the amount of approximately $2.5 million to conduct the ORCA-V1 Phase 2 clinical study evaluating cytisinicline in 160 adult nicotine e-cigarette users in the United States. The full grant award of $2.8 million covered approximately half of the ORCA-V1 clinical study costs. If amounts allocated to federal grants were reduced or eliminated, we would be required to fund the shortfall in the ORCA-V1 clinical study costs.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of fraud or misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, or CROs, which could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, report financial information or data accurately, or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition and results of operations, including the imposition of significant fines or other sanctions. Further, even if we are successful in asserting a defense, we may incur substantial costs in preparing and maintaining our defense and any such action would be time- and resource-intensive and potentially divert management's attention from the business, which could adversely affect our business and results of operations.

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 EU (including the U.K.) 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 chairman Richard Stewart and our executive officers John Bencich, Cindy Jacobs, Anthony Clarke, Jaime Xinos and Craig Donnelly. In addition, although we have entered into employment agreements with each of Mr. Stewart, Mr. Bencich, Dr. Jacobs, Dr. Clarke, Ms. Xinos and Mr.Donnelly, such agreements permit those executives to terminate their employment with us at any time, subject to providing us with advance written notice.

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

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

We may need to expand our organization, which may require us to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively

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

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

In the future, we may invest in the research and development of new indications for cytisinicline to address nicotine addictions associated with the use of e-cigarette, or vaping, products. Given their recent introduction, the use of vaping products is not fully understood which may increase the risk of failure in this area. We are pursuing clinical studies in users of e-cigarettes and have been awarded a grant by the NIDA/NIH to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. Continued grant funding under the award will still be subject to availability of funds at the NIDA/NIH, and such funding will not be sufficient to cover the full clinical costs of the Phase 2 ORCA-V1 trial. We expect that we will need to invest significant amounts of capital to pursue development of an e-cigarette cessation indication. If we are unable to provide such additional capital when needed, we may be unable to complete the development, regulatory approval and commercialization of an e-cigarette cessation indication.

The development of additional indications for cytisinicline is highly uncertain. During the research and development cycle, we may expend significant time and resources on developing additional indications without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of additional indications, and failure can occur at any point in the process, including late in the process after substantial investment. Further, any new indications may not be accepted by physicians and the medical community at large, and competitors may develop and market equivalent or superior products. Failure to launch commercially successful new indications for cytisinicline after significant investment could have a material adverse effect on our business, financial condition and results of operations.

Our internal computer systems, or those of our third-party collaborators or other service providers, may fail or suffer security breaches and cyber-attacks, which could result in a material disruption of our development programs.

We believe that we take reasonable steps that are designed to protect the security, integrity and confidentiality of the information we collect, use, store, and disclose, but inadvertent or unauthorized data access may occur despite our efforts. Our system protections may be ineffective or inadequate, or we could be impacted by software bugs or other technical malfunctions, as well as employee error or malfeasance. Additionally, privacy and data protection laws are evolving, and it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data handling safeguards and practices that could result in fines, lawsuits, and other penalties, and significant changes to our or our third-party collaborators or service providers business practices and products and service offerings. To the extent that the measures we or our third-party collaborators or service providers have taken prove to be insufficient or inadequate, we may become subject to litigation, breach notification obligations, or regulatory or administrative sanctions, which could result in significant fines, penalties, damages, harm to our reputation, or loss of customers. While we have not experienced any material losses as a result of any system failure, accident or security breach to date, we have been the subject of certain phishing attempts in the past. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. Additionally, a party who circumvents our security measures could, among other effects, appropriate patient information or other proprietary data, cause interruptions in our operations, or expose our collaborators to hacks, viruses, and other disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, insurance coverage to compensate for any losses associated with such events, if available, may not be adequate to cover all potential losses. The

development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.

To the extent that any disruption, security breach, or cyber-attack were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidate could be delayed. Depending on the nature of the information compromised, in the event of a data breach or other unauthorized access to our patient data, we may also have obligations to notify patients and regulators about the incident, and we may need to provide some form of remedy, such as a subscription to credit monitoring services, pay significant fines to one or more regulators, or pay compensation in connection with a class-action settlement (including under the new private right of action under the California Consumer Privacy Act of 2018). Such breach notification laws continue to evolve and may be inconsistent from one jurisdiction to another. Complying with these obligations could cause us to incur substantial costs and could increase negative publicity surrounding any incident that compromises customer data. Additionally, the financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain or obtain in the future, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have an adverse effect on our business, reputation, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties to manufacture cytisinicline. We currently exclusively rely on Sopharma to manufacture cytisinicline for use in clinical trials and plan to engage other third parties for our manufacturing process, including to manufacture cytisinicline on a commercial scale, 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 internal infrastructure or capability 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 engage other third parties for our manufacturing process, including, if cytisinicline is approved, to manufacture cytisinicline on a commercial scale, with tableting, blistering and packaging. We may encounter technical difficulties or delays in the transfer of cytisinicline manufacturing on a commercial scale to other third-party manufacturers, encounter difficulties and delays in identifying third-party manufacturers other than Sopharma. We may be unable to enter into agreements for commercial supply with third-party manufacturers on acceptable terms, or at all.

Sopharma and potential other third-party manufacturers are subject to regulatory requirements covering manufacturing, testing, quality control and record keeping relating to product candidates and are also subject to ongoing inspections by regulatory agencies. While Sopharma has been subject to oversight by regulators in Europe and Bulgaria, they have never been inspected by the FDA and there is no assurance that their quality systems will be satisfactory to pass a pre-approval inspection by the FDA. Failure by Sopharma or any of our potential third-party manufacturers to comply with applicable regulations may result in long delays and interruptions to our product candidate supply while we seek to secure another supplier that meets all regulatory requirements.

Our reliance on Sopharma and potential other third-party manufacturers exposes us to the following additional risks:

- Sopharma and potential other third-party manufacturers might be unable to timely manufacture cytisinicline or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Sopharma and potential other third-party manufacturers may not be able to execute our manufacturing procedures appropriately;
- Sopharma and potential other third-party manufacturers 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 and potential other third-party manufacturers are 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, or other third parties', 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 and potential other third-party manufacturers in the manufacturing process for cytisinicline;

- we do not own all the intellectual property rights to cytisinicline, and Sopharma and potential other third-party manufacturers could license such rights to third parties or begin supplying other third parties with cytisinicline; and
- Sopharma and potential other third-party manufacturers 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 the 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. For example, the military conflict between Russia and Ukraine may increase the likelihood of supply interruptions and hinder our ability to find the materials we need to make our product candidate. 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.

In June 2021, Pfizer Inc. halted the distribution of its smoking cessation drug, Chantix (varenicline), after heightened levels, above the FDA's acceptable daily intake limit, of nitrosamines were found in some lots of Chantix pills. In September 2021, Pfizer announced a nationwide recall in the United States of all lots of Chantix and have also withdrawn the product in other countries around the globe. We have undertaken a review of cytisinicline in accordance with regulatory guidance to assess the risk of the presence of nitrosamine and other potential impurities. If contaminants, or impurities such as nitrosamines, are discovered in quantities above regulators' thresholds within our supply of cytisinicline, we may potentially delay product development and approval or have a material adverse impact on our business.

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.

We may rely on third parties to perform many essential services for any of our current or future product candidates that we commercialize, including services related to warehousing and inventory control, distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize any of our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of any of our current or future product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to warehousing and inventory control, distribution, government price reporting, customer service, accounts receivable management, and cash collection, and, as a result, most of our inventory may be stored at a single warehouse maintained by one such service provider. If we retain a service provider, we would substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, if a third-party errs in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability and potentially cause government programs to overpay providers for our products, which could expose us to significant False Claims Act liability and other civil monetary penalties.

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 products for smoking cessation and 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. 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.

We have and will continue to pursue new cytisinicline products and alternative sources of cytisinicline used for our products, including additional natural and synthetic sources and routes. The pursuit and development of alternative cytisinicline products and sources is expensive, time consuming, involves significant risk and may not be commercially feasible. There is no guarantee that we will be successful, or that we will be able to develop new products or alternative cytisinicline sources first before our competitors do.

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

Even if cytisinicline displays a favorable efficacy and safety profile upon approval, market acceptance of cytisinicline remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of cytisinicline, if any, may require significant investment and resources and may never be successful. Additionally, third-party payors, including governmental and private insurers, may also encourage the use of generic products instead of cytisinicline, or a generic version of cytisinicline, which require a prescription or may be available OTC. 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 eligible for composition of matter patents in the United States as it is a naturally occurring substance. As such, third parties are able to manufacture, sell or distribute cytisinicline without royalties or other payments to us and compete with our products in the United States and potentially worldwide and negatively impact our commercialization efforts of our products. We are aware of additional cytisinicline products approved in several European countries and we may not be able to block other third parties from launching generic versions of cytisinicline. Third parties may also sell or distribute cytisinicline as an herbal or homeopathic product. Other than regulatory exclusivity or other limitations, there may be little to nothing to stop these third parties from manufacturing, selling or distributing cytisinicline. Because we have no ability to set rigorous safety standards or control processes over third party manufacturers, sellers or distributors of cytisinicline, excluding Sopharma, these formulations of cytisinicline may be unsafe or cause adverse effects to patients and negatively impact the reputation of cytisinicline as a safe and effective smoking cessation aid.

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

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe cytisinicline products could materially affect patient confidence in our cytisinicline product. It is possible that adverse events caused by unsafe counterfeit or other cytisinicline products that we do not produce will mistakenly be attributed to our cytisinicline product. In addition, thefts of inventory that are not properly stored at warehouses, plants or while in-transit, 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 is currently approved for sale in certain Central and Eastern European countries. Cytisinicline has not yet received a marketing approval from the FDA, and we intend to conduct the requisite clinical trials to obtain approval for the marketing of cytisinicline in the United States and in major global markets. We are aware that products purporting to be Sopharma’s cytisinicline brand 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 EU.

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.

Even if we obtain regulatory approval in the United States or elsewhere to market any of our products, the commercial success of our products and our financial prospects will depend in part on the extent to which the costs of our products will be covered by third-party payors for prescription medications.

Third-party payors, such as government health care programs, private health insurers, managed health care providers and other organizations, are increasingly challenging medical product prices and examining the medical necessity and cost-effectiveness of medical products, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, even if they do, the level of payment may not be sufficient to allow us, or a commercial partner, to sell our products on a profitable basis. If third-party payors do not provide adequate coverage and reimbursement, health care providers may not prescribe our products or patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Significant uncertainty exists as to the reimbursement status for newly approved prescription products, including coding, coverage and payment. There is no uniform policy requirement for coverage and reimbursement for prescription products among third-party payors in the United States; therefore, coverage and reimbursement for our products could differ significantly from payor to payor. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

To secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product to third-party payors, which costs would be in addition to those required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Accordingly, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payor will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for health care providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use.

Additionally, the containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the United States will continue to consider legislation directed at lowering the total cost of health care. Individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

The Biden Administration has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful. It is uncertain whether and how future legislation or regulatory changes, to the ACA and otherwise, could affect prospects for our product candidates or what actions third-party payors may take in

response to any such health care reform proposals or legislation. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates. Currently, the ACA and other federal laws and rules require most health insurance plans in the United States to cover some level of tobacco cessation treatments, including smoking cessation counseling and medications. If these provisions are repealed, in whole or in part, our business, financial condition, or results of operations could be negatively affected.

Failure by us or a commercial partner to obtain timely or adequate coverage and pricing for our products, if approved, or obtaining such coverage and pricing at unfavorable levels, could materially adversely affect our business, financial conditions, results of operations and prospects.

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 intellectual property through trade secrets, licenses, patents from third parties, and patents and 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 in treating nicotine dependence for smoking cessation in adults. 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 United States 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 U.S. Patent and Trademark Office, or 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 in part 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 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 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 *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.

It is difficult and costly to protect our proprietary rights and as a result we may not be able to ensure their protection. In addition, patents have a limited lifespan and will eventually expire.

Market exclusivity awarded by the FDA upon the approval of an NDA is limited in scope and duration. Our commercial success will depend in part on obtaining, maintaining, enforcing, and defending against third-party challenges, patent and trade secret protection for our current and future product candidates that we may develop, license or acquire, as well as the related manufacturing methods. We will be able to protect our technologies from unauthorized use by third parties to the extent that the technologies are covered by valid and enforceable patents or trade secrets.

The patent prosecution 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. 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. Moreover, should we enter into additional collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance, and enforcement of our patent applications and patents. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents and patent applications or in third-party patents and patent applications. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the patent application process is also subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting any of our current or future product candidates that we may develop, license, or acquire by obtaining and defending patents. For example:

- we may not have been the first to conceive of and reduce to practice the inventions covered by each of our pending patent applications and issued patents;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications will result in issued patents;
- the issued patents may not cover commercially viable active products, may not provide us with any competitive advantages, or may be successfully challenged by third parties;
- we may not develop additional proprietary technologies that are patentable;
- patents of others may have an adverse effect on our business;

•noncompliance with requirements of governmental patent agencies can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, potentially allowing competitors to enter the market earlier than would otherwise have been the case;

•our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates; or

•there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of available patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

Patents have a limited lifespan. In most countries, including the United States, the expiration of a patent is typically 20 years from the date that the application for the patent is filed. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the USPTO and the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents or patent applications will be due to be paid to the USPTO and various patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ and rely on reputable law firms and other professionals to effect payment of these fees to the USPTO and non-U.S. patent agencies for the patents and patent applications we own and those that we in-license. We also employ reputable law firms and other professionals to help us comply with the various documentary and other procedural requirements with respect to the patents and patent applications that we own and those that we in-license. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our issued patents, our in-licensed patents, or other intellectual property that we own or in-license. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part; construe the patent's claims narrowly; or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Most of our competitors are larger than we are and have substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into development partnerships that would help us bring our product candidates to market.

We or our licensors may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patent applications and patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our or our licensors' intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Common Stock

The price for our common stock is volatile.

The market prices for our common stock and that of 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 and geopolitical conditions, including the current global economic recession, increasing inflation and interest rates, and the increasingly volatile global economic conditions resulting from global conflicts;

•sales of our common stock us or our stockholders in the future;

•trading volume of our common stock;

•adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;

•changes in the structure of healthcare payment systems;

•period-to-period fluctuations in our financial results; and

•tweets or other social media posts related to our market and industry.

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

A significant portion of our total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well, and result in significant dilution to our stockholders.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, either by us or our stockholders. These sales, or the perception in the market that we or holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

In May 2023, we entered into the $16.6 million Debt Agreement with the Lenders. Subject to certain terms and conditions, the Lenders may convert all or any part of the outstanding Convertible Term Loan and accrued and unpaid interest at any time prior to maturity into shares of our common stock at a conversion price equal to $9.34 per share, subject to customary anti-dilution adjustments. Additionally, all outstanding amounts under the Convertible Term Loan, including accrued and unpaid interest, will mandatorily convert into shares of our common stock, at the conversion price, on such date, if any, when the closing price per share of our common stock has been equal to or greater than $24.00 for 30 consecutive trading days prior to such date. We are aware that there can be no assurance that the Term Loans will be available to us for borrowing nor whether the Lenders will be willing to work with us on any modifications to the current Convertible Term Loan or Debt Agreement.

As of December 31, 2023, there were 1,461,980 shares of our common stock subject to outstanding options and 507,875 subject to outstanding restricted stock units, almost all of which have been registered under the Securities Act on Form S-8. The shares so registered can be freely sold in the public market after being issued to the option holder upon exercise, except to the extent they are held by an affiliate of ours, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of December 31, 2023, there were approximately 4,946,171 shares of our common stock subject to outstanding warrants to purchase common stock, with a weighted average exercise price of $5.48 per share, and 142,857 shares of our common stock subject to outstanding pre-funded warrants, with an exercise price of $0.001 per share. To the extent any of these warrants are exercised, the shares underlying these warrants may be immediately sold in the public market. In February 2024, we announced the sale and issuance of warrants to purchase up to 13,086,151 shares of common stock (or pre-funded warrants), with an exercise price of $4.906 per share (or $4.905 per pre-funded warrant), in a concurrent private placement with the sale of 13,086,151 shares of common stock sold in a registered direct offering. We expect to register the shares underlying these warrants (or pre-funded

warrants) for resale. If, following such registration, these shares are issued upon exercise of the warrants (or pre-funded warrants), they may be immediately sold in the public market.

The sale of additional shares of our common stock, the conversion of the Convertible Term Loan into shares of our common stock, the exercise of any of our outstanding warrants, the exercise of any of our outstanding options, or the settlement of our restricted stock units would have a dilutive impact on our existing stockholders and could cause the market price of our common stock to decline significantly. Sales of our common stock, the conversion of the Convertible Term Loan, the exercise of any of our outstanding warrants, the exercise of any of our outstanding options, the settlement of our restricted stock units or the perception that such events will occur, could also encourage short sales by third parties, which could contribute to the further decline of the price of our common stock. Additionally, the sale of a substantial number of shares of our common stock, the conversion of the Convertible Term Loan, the exercise of any of our outstanding warrants, the exercise of any of our outstanding options, the settlement of our restricted stock units or the perception that such events will occur, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish.

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

Because our 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 2017 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.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the equity research analysts that provide research coverage of our common stock or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrades our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

General Risk Factors

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.

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

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

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

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

Shareholder activists could cause a disruption to our business.

An activist investor may indicate disagreement with our strategic direction or capital allocation policies and may seek representation on our board of directors. Our business, operating results or financial condition could be adversely affected and may result in, among other things:

- increased operating costs, including increased legal expenses, insurance, administrative expenses and associated costs incurred in connection with director election contests;

- uncertainties as to our future direction, which could result in the loss of potential business opportunities and could make it more difficult to attract, retain, or motivate qualified personnel, and strain relationships with investors and customers; and

- reduction or delay in our ability to effectively execute our current business strategy and to implement new strategies.

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.

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 Exchange Act, 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.

Failure to maintain effective internal control over financial reporting could have a material adverse effect on our reputation, results of operations and financial condition.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports, prevent fraud and operate successfully as a public company. Any failure to execute on our internal controls and continue to maintain effective internal controls, to timely implement any necessary additional improvement to our internal controls or to effect remediation of any future material weakness or significant deficiency could, among other things, result in losses from fraud or error, harm our reputation or cause investors to lose confidence in our reported financial information, all of which could have a material adverse effect on our reputation, results of operations, or financial condition.

Management reviews and updates our systems of internal controls and procedures, as appropriate. Any system of controls is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of our controls and procedures or failure to comply with regulations related to controls and procedures could have a material adverse effect on our reputation, results of operations and financial condition.

U.S. federal tax reform and changes in other tax laws could increase our tax burden and adversely affect our business and financial condition.

In December 2017, the U.S. government enacted comprehensive tax legislation, the Tax Cuts and Jobs Act of 2017, significantly reforming the Internal Revenue Code of 1986, as amended. 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, tax legislation requires research and experimental expenditures to be capitalized and amortized ratably over a five-year period. Any such expenditures attributable to research conducted outside the United States 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. Furthermore, it is uncertain if and to what extent various states will conform to the enacted federal tax law or any newly enacted federal legislation. In addition, new legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

Our process for managing cybersecurity risk is comprised of technologies, controls, and procedures designed to detect, assess, and manage threats and control access. We utilize a variety of systems, software, and services including firewalls, network and endpoint monitoring, anti-malware, detection and response, patch management, and backups to mitigate, identify, analyze, and respond to identified vulnerabilities and incidents in a timely manner.

We evaluate our security posture on an ongoing basis via vulnerability scans, penetration testing, and threat intelligence monitoring. We periodically conduct third-party security assessments and regularly evaluate our processes against industry standard security frameworks. We conduct regular security training to elevate awareness and foster a security conscious culture among all employees.

We leverage third party service providers and solutions in many aspects of our operations. Our vendor management and oversight procedures include assessment of cyber security risk.

We do not believe there are any currently known cybersecurity risks that are reasonably likely to materially impact our business strategy, operations, or financial condition. If we were to experience a material cybersecurity incident in the future, such incident may have an adverse effect, including on our business operations, operating results, or financial condition. For more information regarding cybersecurity risks that we face and the related potential impacts on our business, see the risk factor titled "***Our internal computer systems, or those of our third-party collaborators or other service providers, may fail or suffer security breaches and cyber-attacks, which could result in a material disruption of our development programs.***"

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes and an area of increasing focus for our board of directors, or Board, and management.

The Audit Committee of our Board, or Audit Committee, is responsible for the oversight of risks from cybersecurity threats. At least annually, the Audit Committee receives an overview from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. Members of the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Potential material cybersecurity threat risks are also considered during Board meeting discussions of important matters like risk management, business continuity planning, and other relevant matters.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including our Senior Director of Information Technology who has served in various roles managing information technology and information security for over twenty-five years and reports directly to the Chief Executive Officer.

Management is also responsible for hiring appropriate personnel, integrating cybersecurity considerations into our overall risk management strategy, and for communicating key priorities to employees, as well as for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management processes involve management, who participates in our disclosure controls and procedures. Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents and vulnerabilities to members of management depending on the circumstances, including work with the company's incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, the company's incident response processes include reporting to the Audit Committee for certain cybersecurity incidents.

Management is involved with our efforts to prevent, detect, and mitigate cybersecurity incidents by overseeing preparation of cybersecurity policies and procedures, testing of incident response plans, and engagement of vendors to conduct penetration tests. Management participates in cybersecurity incident response efforts by being a member of the incident response team and helping direct our response to cybersecurity incidents.

ITEM 2. PROPERTIES

We have a business office located in Vancouver, British Columbia.

On November 19, 2018, we entered into a lease agreement for our office space in Vancouver, British Columbia, which commenced on February 1, 2019, and had a four-year term. On December 16, 2022, we entered into an agreement to extend the lease for another

two-year term, which commenced on February 1, 2023. Pursuant to this lease, we rent approximately 2,367 square feet of office space. The annual rent is approximately $0.1 million.

On November 9, 2023, we entered into a lease agreement for our office space in Bothell, Washington, which commenced on March 1, 2024, and had a one-year term. The annual rent is approximately $15,400.

We believe that the facility we currently lease is 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 a corporate transaction and name change, 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 March 18, 2024, there were approximately 18 stockholders of record. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares of record are held by banks, brokers, and other financial institutions.

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, 2023 were made by us or on our behalf.

On August 29, 2023, we issued 60,000 unregistered shares of common stock pursuant to Section 4(a)(2) of the Securities Act to one of our vendors as part of a non-monetary barter transaction for the settlement of trade payables owed.

ITEM 6. RESERVED

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including but not limited to those discussed in the section titled "Risk Factors" and in other parts of this Annual Report on Form 10-K. A discussion and analysis of our financial condition, results of operations, and cash flows for the year ended December 31, 2022 compared to the year ended December 31, 2021 is included in Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 16, 2023.

Overview

Our focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. There are an estimated 28 million adults in the United States alone who smoke combustible cigarettes. Tobacco use is currently the leading cause of preventable death and is responsible for more than 8.0 million deaths worldwide and nearly half a million deaths in the United States annually. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.

In addition, there are approximately 11.0 million adults in the United States who use e-cigarettes, also known as vaping. While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease. In 2023, 2.1 million high school and middle school students reported using e-cigarettes. Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped. Currently, there are no U.S. Food and Drug Administration, or FDA, approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine addiction and has not been approved by the FDA for any indication in the United States.

Cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. If approved by the FDA, it stands to become the first new prescription medicine in nearly two decades aimed at aiding individuals in overcoming nicotine dependence. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of robust efficacy, minimal frequency of side effects and optional shorter course of therapy.

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 $29.8 million for the year ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of $165.8 million, cash and cash equivalents balance of $15.5 million and a negative working capital balance of $3.8 million. During the year ended December 31, 2023, net cash used in operations was $24.5 million.

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. 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, certain cytisinicline trademarks 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 cytisinicline 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.

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma AD to acquire 75% of the outstanding shares of Extab Corporation for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the FDA or the European Medicines Agency, or EMA. The fair value of the contingent consideration on the acquisition date was nil. The contingent consideration liability is measured at fair value in our financial statements,

As of December 31, 2023, the fair value of the contingent consideration was estimated to be $0.5 million (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated Financial Statements). We recognized a loss of $0.5 million for the year ended December 31, 2023.

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, 2023, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Research and Development Expenses

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

We manage our clinical trials through contract research organizations and independent medical investigators at our sites and at hospitals and expect this practice to continue. Due to our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs incurred for our R&D 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 R&D 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 our 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 expenses consist primarily of salaries and related costs for our personnel in executive, finance and accounting, corporate communications and other administrative functions, as well as consulting costs, including market research, business consulting, human resources and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs.

Results of Operations

Years Ended December 31, 2023 and 2022

Research and Development Expenses

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

	Year Ended December 31,	
	2023	2022
Clinical development programs:		
Cytisinicline	$ 15,814	$ 30,078
Total research and development expenses	**$ 15,814**	**$ 30,078**

Research and development expenses for the years ended December 31, 2023 and 2022 were $15.8 million and $30.1 million, respectively. The decrease in 2023 as compared to 2022 was primarily due to the timing of completion and wind down of our Phase 3 ORCA-3 trial in May 2023 and Phase 2 ORCA-V1 trial in April 2023. This was partially offset by higher costs associated with an increase in NDA-supporting activities including initiation and enrollment in other clinical studies for renal impairment, QT interval prolongation and other remaining PK parameters, manufacturing and FDA readiness activities.

General and Administrative Expenses

Our general and administrative expenses were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Total general and administrative expenses	**$ 11,436**	**$ 10,722**

G&A expenses for the years ended December 31, 2023 and 2022 were $11.4 million and $10.7 million, respectively. The increase in 2023 as compared to 2022 was primarily due to higher employee expenses associated with stock-based compensation, higher legal expenses as a result of general corporate activities, an increase in investor relations activities and commercial market planning activities. The increased expenses were partially offset by a decrease in costs associated with clinical trial media and awareness as both the ORCA-3 trial and ORCA-V1 trial were fully enrolled in the third and fourth quarter of 2022, respectively, and lower patent filing expenses as a result of a decrease in patent-associated activities in 2023.

Other Income (Expenses)

Other expenses for the years ended December 31, 2023 and 2022 were $2.6 million and $1.6 million, respectively. The increase in 2023 as compared to 2022 was due to an increase in interest expense on our convertible debt as a result of higher interest rates in 2023 and compounding of the accrued paid-in-kind interest and change in the fair value of the Sopharma contingent consideration liability. This was partially offset by higher interest income in 2023 as a result of higher interest rate yields.

Liquidity and Capital Resources

We have incurred an accumulated deficit of $165.8 million through December 31, 2023 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, 2023, we had a cash and cash equivalents balance of $15.5 million and a negative working capital balance of $3.8 million. For the year ended December 31, 2023, net cash used in operations was $24.5 million. We have historically financed our operations through equity financings. While we believe that we will be able to settle our commitments and liabilities in the normal course of business as they fall due during the next 12 months, as a development-stage company with no current sources of revenue, we are dependent on our ability to raise funds (through public or private securities offerings, debt financings, government funding or grants, or other sources, which may include licensing, collaborations or other strategic transactions or arrangements) to support the ongoing advancement of our clinical trials and corporate activities. We believe that our existing cash and cash equivalents, which includes net proceeds of approximately $56.2 million from our February 2024 registered direct offering, will be sufficient for us to fund our current operating expenses and capital expenditures into the second half of 2025, including through potential NDA submission to the FDA for cytisinicline and the potential repayment of our outstanding debt obligations under our contingent convertible term loan.

Convertible Debt

On December 22, 2021, we entered into a $25.0 million contingent convertible debt agreement, or Original Debt Agreement, with Silicon Valley Bank, or SVB, and SVB Innovation Credit Fund VIII, L.P., or, together with SVB, the Lenders. As part of the Original Debt Agreement, the Lenders funded $15.0 million in the form of convertible indebtedness, or Convertible Debt, at closing. On April 26, 2022, we entered into (i) a loan and security agreement, or Loan Agreement, with SVB for the remaining $10.0 million remaining in the Original Debt Agreement, pursuant to which SVB provided a commitment to extend term loans having an aggregate original principal amount of up to $10.0 million, or Term Loans, and (ii) a first amendment to the Original Debt Agreement, or the Amendment, and as amended by the Amendment, the Debt Agreement. The availability of Term Loans under the Loan Agreement expired on April 30, 2023, with no amounts drawn under the facility.

On May 15, 2023, we entered into a contingent convertible debt agreement, or Debt Agreement, with the Lenders, pursuant to which the Lenders provided term loans having an aggregate original principal amount of $16.6 million, or the Convertible Term Loan. The Convertible Debt under the Original Debt Agreement was refinanced as the Convertible Term Loan pursuant to the Debt Agreement. Our obligations under the Loan Agreement, Original Debt Agreement and Convertible Debt were satisfied in full and the Loan Agreement, Original Debt Agreement and Convertible Debt were terminated in connection with the entrance into the Debt Agreement and Convertible Term Loan.

The Convertible Term Loan matures on December 22, 2024; provided that (a) in the event we fail to receive written notice, or a Filing Communication, that the FDA has accepted for filing our New Drug Application, or NDA, with respect to cytisinicline for a smoking cessation indication, on or prior to July 31, 2024, the maturity date shall be August 1, 2024 or (b) in the event we receive a Filing Communication with respect to cytisinicline for a smoking cessation indication on or prior to August 14, 2024, but where such Filing Communication specifies any material deficiencies or material filing review issues with respect to such NDA, the maturity date shall be August 15, 2024; provided, further, that in the event we have submitted the NDA on or prior to June 30, 2024, the dates listed in (a) and (b) above shall be extended by one calendar month. Interest is calculated on the outstanding principal amount of the Convertible Term Loan at the aggregate of (a) a floating rate per annum equal to the greater of (i) 2.25% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears, and (b) 7.0% per annum, compounded monthly, which shall be payable on the earlier to occur of the maturity date and the date that the Convertible Term Loan is converted into our common stock.

Subject to certain terms and conditions, the Lenders may convert all or any part of the outstanding Convertible Term Loan principal and accrued and unpaid interest at any time prior to maturity into shares of our common stock at a conversion price equal to $9.34 per share, subject to customary anti-dilution adjustments. Additionally, all outstanding Convertible Term Loan principal and accrued and unpaid interest will mandatorily convert into shares of our common stock, at the conversion price, on such date, if any, when the closing price per share of our common stock has been equal to or greater than $24.00 for thirty consecutive trading days prior to such date.

We have the right, or Call Right, at any time to repay and retire all (but not less than all) of the outstanding Convertible Term Loan and accrued and unpaid interest, if any, prior to its conversion by payment of a premium equal to 150% of the outstanding principal balance (including any compounded interest), plus accrued and unpaid interest; provided, however, that we may not exercise the Call Right at any time when the Liquidity Conditions (as defined in the Debt Agreement) are not satisfied.

Notwithstanding the foregoing, if we (x) elect to repay the Lenders and (y) in the twelve month period following such repayment, (i) enter into an agreement or similar commitment, binding or nonbinding, with any third party respecting an acquisition, and (ii) such acquisition is subsequently consummated, if the aggregate gross proceeds that would have been payable to the Lenders or, pursuant to an assignment, any designee thereof, or collectively, the Conversion Rights Holders, in connection with such acquisition had we not repaid the Convertible Term Loan and the Conversion Right Holders had exercised, in connection with such acquisition, the right to convert the Convertible Term Loan into shares of our common stock, then (z) we shall pay to the Lenders as an additional call price, the difference between such proceeds as would have been payable to the Conversion Right Holders in connection with such acquisition and the payment actually paid to the Lenders.

The Debt Agreement contains customary affirmative and restrictive covenants, including covenants regarding the incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, mergers or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. The Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lenders may not engage in any short sales of, or other hedging transactions in, our common stock while any amounts are outstanding under the Debt Agreement. Our obligations under the Debt Agreement are secured by substantially all of our assets, other than intellectual property.

On February 26, 2024, we entered into a non-binding term sheet, or the Term Sheet, for an extension of the maturity date for the term loans outstanding pursuant to our Debt Agreement with Lenders. There is no guarantee that we will be able to enter into a definitive agreement with the Lenders on the terms provided in the Term Sheet or any at all. (See “Item 1A. Risk Factors - Risks Related to Our Financial Condition and Capital Requirements").

At-the-Market Sales Agreement

On December 21, 2021, we entered into an At-the-Market Offering Sales Agreement, or ATM, with Virtu Americas, LLC, as sales agent, pursuant to which from December 21, 2021 through December 31, 2023, we offered and sold an aggregate of 200,000 shares of our common stock. These aggregate sales resulted in gross proceeds to us of approximately $1.5 million. During the year ended December 31, 2023, we did not sell any shares of our common stock pursuant to the ATM. The ATM was subsequently terminated on February 29, 2024, and no further sales of our common stock will be made pursuant to the ATM.

November 2022 Private Placement

In November 2022, we entered into subscription agreements with certain accredited investors pursuant to which we sold to the purchasers in a private placement transaction approximately 4,093,141 units at a purchase price of $4.625 per unit, with each unit consisting of two shares of common stock and a common stock purchase warrant to purchase one share of common stock, or the Warrants.

The Warrants are exercisable at a price per share of common stock of $4.50, subject to adjustment. The Warrants are exercisable beginning on the six-month anniversary of the initial closing date of the private placement offering, or May 18, 2023, or the Initial Exercise Date, and will expire on the seven year anniversary of the initial closing date of the private placement offering, or November 18, 2029. The Warrants cannot be exercised by a Warrant holder if, after giving effect thereto, such Warrant holder would beneficially own more than 19.99% of our outstanding common stock. Additionally, subject to certain exceptions, if, after the Initial Exercise Date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the Measurement Period, which Measurement Period commenced on November 18, 2022, 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.

We received approximately $17.9 million in net proceeds from the private placement after deducting placement agent expenses and commissions and offering expenses.

May 2023 Registered Direct Offering

In May 2023, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 3,000,000 shares of common stock at a price of $5.50 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3 including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated May 25, 2023.

We received approximately $15.3 million in net proceeds from the registered direct offering after deducting placement agent fees and offering expenses.

February 2024 Registered Direct Offering and Concurrent Private Placement

In February 2024, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 13,086,151 shares of common stock at a price of $4.585 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3, including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated February 29, 2024.

In a concurrent private placement, we issued unregistered warrants to purchase up to 13,086,151 shares of common stock at an exercise price of $4.906 per share (provided, however, that the purchaser may elect to exercise the warrants for pre-funded warrants in lieu of shares of common stock at an exercise price of $4.906, minus $0.001, the exercise price of each pre-funded warrant). These warrants will be immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof, and will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following our public disclosure of the acceptance of an NDA for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence.

The registered direct offering raised total gross proceeds of approximately $60.0 million, and after deducting approximately $3.8 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.2 million.

Cash Flows

Operating Activities

For the years ended December 31, 2023 and 2022, net cash used in operating activities was $24.5 million and $37.6 million, respectively. The decrease in cash used in operations in the 2023 period as compared to the 2022 period was primarily attributable to lower R&D expense in 2023 as a result of the timing of the completion and wind down of our Phase 3 ORCA-3 trial in May 2023 and Phase 2 ORCA-V1 trial in April 2023. The decrease was partially offset by an increase in NDA-supporting activities including initiation and enrollment in other clinical studies for renal impairment, QT interval prolongation and other remaining PK parameters, manufacturing and FDA readiness activities.

Financing Activities

For the years ended December 31, 2023 and 2022 net cash provided by financing activities was $15.3 million and $19.3 million, respectively. Net cash provided by financing activities for the year ended December 31, 2023 relates to proceeds received from our May 2023 private placement and warrant exercises. Net cash provided by financing activities for the year ended December 31, 2022 relates to proceeds received from our November 2022 private placement, ATM sales, stock sales under our employee stock purchase plan and warrant exercises.

Investing Activities

Investing activities in 2023 consisted of property and equipment purchases. There were no investing activities in 2022.

Critical Accounting Policies and Estimates

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 contingent considerations, 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.

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.

Sopharma Share Purchase Agreement Contingent Consideration

We may be required to pay future contingent consideration to Sopharma, AD as part of the Share Purchase Agreement, which is contingent upon obtaining regulatory approval of cytisinicline by the FDA or the EMA.We determine the fair value of the contingent consideration using a probability based discounted cash flow approach whereby we forecast the timing of the cash flow of the related future payment based on cytisinicline's current clinical development phase and the remaining requirements for regulatory approval. We then discount the expected payment amount to calculate the present value and then apply a probability of success in obtaining regulatory approval as of the valuation date. We evaluate the underlying projection used in determining the fair value each period and make updates as necessary.

The significant assumptions we use to value the contingent consideration are the forecasted timing of the future payment, the risk-adjusted discount rate and the probability of success which are all considered significant unobservable inputs, and as such, the liability is classified as a Level 3 measurement. The risk-adjusted discount rate is adjusted for credit risk. An increase in the discount rate or decrease in the probability of success would result in a decrease in the fair value of the contingent consideration. Conversely, a decrease in the discount rate or increase in the probability of success would result in an increase in the fair value of the contingent consideration.

Government Grants

We account for government grants by recognizing the benefit of the grant as qualifying expenditures are incurred provided that there is reasonable assurance that we have complied with all conditions under the terms of the grant and that the amount requested for reimbursement will be received. The government grant reduces the research and development expenses to which it relates on our statement of profit and loss.

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

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

Restricted Stock Unit Awards

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

Warrants

We account for warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and 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 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.

Recent Accounting Standards

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are required for all entities on an interim and annual basis, even if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024 and early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09 “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”. This guidance is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

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, 2023 and 2022, and the related consolidated statements of loss and comprehensive loss, of stockholders' equity, and of cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Contingent consideration arising from the Sopharma share purchase agreement

As described in Notes 2, 6 and 7 to the consolidated financial statements, in 2015 the Company entered into a Share Purchase Agreement with Sopharma AD to acquire 75% of the outstanding shares of Extab Corporation for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the Federal Drug Administration or the European Medicines Agency. As of December 31, 2023, the fair value of the contingent consideration was estimated to be $0.5 million. Management determined the fair value of the contingent consideration using a probability based discounted cash flow model whereby management forecasted the timing of the cash flow of the related future payment based on cytisnicline's current clinical development phase and the remaining requirements for regulatory approval. Management then discounted the expected payment amount to calculate the present value and then applied a probability of success in obtaining regulatory approval as of the valuation date. Management's significant assumptions include the forecasted timing of the future payment, the probability of success and the risk-adjusted discount rate. The discount rate is adjusted for credit risk.

The principal considerations for our determination that performing procedures relating to the contingent consideration arising from the Sopharma share purchase agreement is a critical audit matter are (i) the significant judgments required by management in determining the fair value of the contingent consideration and (ii) a high degree of auditor judgement, subjectivity, and effort in performing

procedures and evaluating management's significant assumptions relating to the probability of success, the risk-adjusted discount rate, and forecasted timing of the future payment. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) reading the agreement related to the contingent consideration, (ii) evaluating the appropriateness of the probability based discounted cash flow model, (iii) testing the completeness and accuracy of underlying data used in the model, and (iv) evaluating the reasonableness of the significant assumptions used by management related to the probability of success, the risk-adjusted discount rate and the forecasted timing of the future payment. Evaluating management's significant assumptions related to the probability of success and the forecasted timing of the future payment involved evaluating whether these assumptions were reasonable by considering the agreement associated with the transaction, industry information regarding clinical trial success rates and drug development timelines, and whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist with the evaluation of the appropriateness of the probability based discounted cash flow model and the reasonableness of the risk-adjusted discount rate.

/s/PricewaterhouseCoopers LLP

Chartered Professional Accountants
Vancouver, Canada
March 28, 2024

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,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents *[note 3 and note 7]*	$ 15,546	$ 24,771
Grant receivable *[note 4]*	111	105
Prepaid expenses and other assets	1,325	2,454
Total current assets	**16,982**	**27,330**
Restricted cash and other assets *[note 7 and note 8]*	92	66
Right-of-use assets *[note 12]*	66	123
License agreement *[note 5 and note 6]*	1,197	1,418
Goodwill	1,034	1,034
Total assets	**$ 19,371**	**$ 29,971**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 618	$ 1,660
Accrued liabilities other	351	403
Contingent consideration *[note 6 and note 7]*	528	—
Accrued clinical liabilities	280	1,729
Accrued compensation	2,311	1,678
Current portion of long-term obligations *[note 12]*	63	58
Convertible debt *[note 7 and note 9]*	16,662	16,071
Total current liabilities	**20,813**	**21,599**
Long-term obligations *[note 12]*	6	69
Total liabilities	**20,819**	**21,668**
Commitments and contingencies *[note 12]*		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value, 9,158 shares designated, zero issued and outstanding at December 31, 2023 and December 31, 2022.	—	—
Series B convertible preferred stock, $0.001 par value, 6,256 shares designated, zero issued and outstanding at December 31, 2023 and December 31, 2022.	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized, 21,165,760 and 17,897,029 issued and outstanding at December 31, 2023 and December 31, 2022, respectively.	90	87
Additional paid-in capital	164,209	144,148
Accumulated deficit	(165,751)	(135,936)
Accumulated other comprehensive income	4	4
Total stockholders' equity	**(1,448)**	**8,303**
Total liabilities and stockholders' equity	**$ 19,371**	**$ 29,971**
Subsequent events *[note 13]*		

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,		
	2023	2022	2021
EXPENSES			
Research and development	$ 15,814	$ 30,078	$ 23,966
General and administrative	11,436	10,722	9,128
Total operating expenses	27,250	40,800	33,094
OTHER INCOME (EXPENSE)			
Interest income	825	199	17
Interest expense *[note 9]*	(2,853)	(1,789)	—
Change in fair value of contingent consideration *[note 6 and note 7]*	(528)	—	—
Other income/(expense)	(9)	40	(75)
Total other income (expense)	(2,565)	(1,550)	(58)
Net loss and comprehensive loss	$ (29,815)	$ (42,350)	$ (33,152)
Basic and diluted net loss per common share *[note 11 [i]]*	$ (1.50)	$ (4.00)	$ (4.08)
Shares used in computation of basic and diluted net loss per common share *[note 11 [i]]*	19,827,354	10,593,034	8,119,836

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, 2020	6,111,735	76	—	—	97,640	4	(60,434)	37,286
Stock-based compensation expense	—	—	—	—	2,187	—	—	2,187
Shares issued on exercise of warrants	50,834	—	—	—	338	—	—	338
Shares issued as settlement with trade vendor	5,114	—	—	—	41	—	—	41
Shares issued - May 2021 public offering	3,285,714	3	—	—	21,340	—	—	21,343
Restricted stock unit settlements	145	—	—	—	(1)	—	—	(1)
Net loss	—	—	—	—	—	—	(33,152)	(33,152)
Balance, December 31, 2021	9,453,542	79	—	—	121,545	4	(93,586)	28,042
Stock-based compensation expense	—	—	—	—	3,270	—	—	3,270
Shares issued on exercise of warrants	3,709	—	—	—	24	—	—	24
Shares issued from purchase agreement with Virtu	200,000	—	—	—	1,330	—	—	1,330
Shares issued as settlement with trade vendor	3,584	—	—	—	26	—	—	26
Restricted stock unit settlements	26,625	—	—	—	—	—	—	—
Restricted stock unit settlements withheld and retired to treasury	(5,605)	—	—	—	(47)	—	—	(47)
Shares issued under employee share purchase plan	28,892	—	—	—	126	—	—	126
Shares issued - November 2022 private placement	8,186,282	8	—	—	17,874	—	—	17,882
Net loss	—	—	—	—	—	—	(42,350)	(42,350)
Balance, December 31, 2022	17,897,029	87	—	—	144,148	4	(135,936)	8,303
Stock-based compensation expense	—	—	—	—	3,439	—	—	3,439
Shares issued on exercise of warrants	98,333	—	—	—	227	—	—	227
Financing costs relating to November 2022 private placement	—	—	—	—	(30)	—	—	(30)
Shares issued - May 2023 private placement	3,000,000	3	—	—	15,298	—	—	15,301
SVB convertible debt refinancing discount	—	—	—	—	1,074	—	—	1,074
Restricted stock unit settlements	139,750	—	—	—	—	—	—	—
Restricted stock unit settlements withheld and retired to treasury	(29,352)	—	—	—	(220)	—	—	(220)
Shares issued as settlement with trade vendor	60,000	—	—	—	273	—	—	273
Net loss	—	—	—	—	—	—	(29,815)	(29,815)
Balance, December 31, 2023	21,165,760	90	—	—	164,209	4	(165,751)	(1,448)

See accompanying notes.

Achieve Life Sciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2023	2022	2021
Operating Activities:			
Net loss	$ (29,815)	$ (42,350)	$ (33,152)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization *[note 5]*	228	236	250
Stock-based compensation *[note 11[c], note 11[d] and note 11[e]]*	3,439	3,270	2,187
Shares issued as settlement with trade vendor	273	26	41
Accrued interest on SVB convertible debt *[note 9]*	1,216	1,170	—
Accretion of discount on modification of debt	430	—	—
Contingent consideration *[note 6 and note 7]*	528	—	—
Changes in operating assets and liabilities:			
Grant receivable *[note 4]*	(6)	48	(153)
Prepaid expenses and other assets	1,176	(931)	(228)
Accounts payable	(1,042)	799	509
Accrued liabilities other	(32)	55	(245)
Accrued clinical liabilities	(1,449)	376	899
Accrued compensation	633	(263)	466
Lease obligation	(58)	(5)	(14)
Net cash used in operating activities	(24,479)	(37,569)	(29,440)
Financing Activities:			
Proceeds from exercise of warrants *[note 11[g]]*	227	24	338
Proceeds from the May 2021 public offering, net of issuance costs *[note 11[b]]*	—	—	21,343
Receipt of convertible debt from SVB *[note 9]*	—	—	14,929
Proceeds from ATM, net of issuance costs *[note 11[b]]*	—	1,330	—
Proceeds from employee stock purchase plan *[note 11[e]]*	—	126	—
Taxes paid related to net share settlement of equity awards	(220)	(47)	—
Proceeds from the November 2022 private placement, net of issuance costs *[note 11[b]]*	(30)	17,882	—
Proceeds from May 2023 private placement, net of issuance costs *[note 11[b]]*	15,301	—	—
Net cash provided by financing activities	15,278	19,315	36,610
Investing Activities:			
Purchase of property and equipment	(21)	—	—
Net cash provided by (used in) investing activities	(21)	—	-
Effect of exchange rate changes on cash	(3)	3	(1)
Net increase (decrease) in cash, cash equivalents and restricted cash	(9,225)	(18,251)	7,169
Cash, cash equivalents and restricted cash at beginning of year	24,821	43,072	35,903
Cash, cash equivalents and restricted cash at end of year	$ 15,596	$ 24,821	$ 43,072

See accompanying notes.

1. NATURE OF BUSINESS, BASIS OF PRESENTATION AND LIQUIDITY RISK

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 and nicotine addiction. We were incorporated in the state of Delaware, and operate out of Seattle, Washington and Vancouver, British Columbia.

Liquidity

We have historically experienced recurring losses from operations and have incurred an accumulated deficit of $165.8 million through December 31, 2023. As of December 31, 2023, we had cash and cash equivalents of $15.5 million and a negative working capital balance of $3.8 million. For the year ended December 31, 2023, we incurred a net loss of $29.8 million and net cash used in operating activities was $24.5 million. In February 2024, we entered into a securities purchase agreement with certain purchasers in a registered direct offering and raised gross proceeds of approximately $60.0 million, and after deducting approximately $3.8 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.2 million. We have historically financed our operations through equity financings. While we believe that we will be able to settle our commitments and liabilities in the normal course of business as they fall due during the next 12 months, as a development-stage company with no current sources of revenue, we are dependent on our ability to raise funds (through public or private securities offerings, debt financings, government funding or grants, or other sources, which may include licensing, collaborations or other strategic transactions or arrangements) to support the ongoing advancement of our clinical trials and corporate activities.

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.

2. 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 contingent considerations, 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.

Fair value of financial instruments

Other financial instruments including 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.

Sopharma Share Purchase Agreement Contingent Consideration

We may be required to pay future contingent consideration to Sopharma, AD as part of the Share Purchase Agreement, which is contingent upon obtaining regulatory approval of cytisinicline by the FDA or the EMA.We determine the fair value of the contingent consideration using a probability based discounted cash flow approach whereby we forecast the timing of the cash flow of the related future payment based on cytisinicline's current clinical development phase and the remaining requirements for regulatory approval. We then discount the expected payment amount to calculate the present value and then apply a probability of success in obtaining regulatory approval as of the valuation date. We evaluate the underlying projection used in determining the fair value each period and make updates as necessary.

The significant assumptions we use to value the contingent consideration are the forecasted timing of the future payment, the risk-adjusted discount rate and the probability of success which are all considered significant unobservable inputs, and as such, the liability is classified as a Level 3 measurement. The risk-adjusted discount rate is adjusted for credit risk. An increase in the discount rate or decrease in the probability of success would result in a decrease in the fair value of the contingent consideration. Conversely, a decrease in the discount rate or increase in the probability of success would result in an increase in the fair value of the contingent consideration.

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.

Government Grants

We account for government grants by recognizing the benefit of the grant as qualifying expenditures are incurred provided that there is reasonable assurance that we have complied with all conditions under the terms of the grant and that the amount requested for reimbursement will be received. The government grant reduces the research and development, or R&D, expenses to which it relates on our statement of profit and loss.

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

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

Restricted Stock Unit Awards

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

Segment Information

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

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 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.

Reporting Currency and Foreign Currency Translation

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 and comprehensive loss.

Recent Accounting Standards

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are required for all entities on an interim and annual basis, even if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024 and early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09 “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”. This guidance is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

3. FINANCIAL INSTRUMENTS AND RISK

Concentration of Cash and Cash Equivalents Risk

We place our cash primarily in commercial checking accounts with various financial institutions. As of December 31, 2023, approximately $0.4 million of our cash and $2.4 million of our cash equivalents (Note 7 – Fair Value Measurements) is held in a single financial institution, SVB, as required by the covenants of our Convertible Debt Agreement (Note 9 – Convertible Debt). Our commercial bank balances exceed federal insurance limits.

We have not experienced any losses in our cash and cash equivalents for the years ended December 31, 2023 and 2022.

Concentration of Credit Risk

For certain of our financial instruments, including cash and cash equivalents, 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 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 expenses are denominated in other than U.S. dollars.

We invest our excess cash in accordance with investment guidelines, which limit our credit exposure for securities 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, 2023 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.

4. GOVERNMENT GRANT

In July 2021, we announced that we were awarded a grant from the National Institute on Drug Abuse, or NIDA, of the National Institutes of Health, or NIH, to evaluate the use of cytisinicline as a treatment for cessation of nicotine e-cigarette use. This initial grant award, in the amount of $0.3 million, commenced on August 1, 2021, and was utilized to complete critical regulatory and clinical operational activities, such as protocol finalization, clinical trial site identification, drug packaging, and submission of a new Investigational New Drug Application, or IND, to the U.S. Food and Drug Administration, or FDA, for investigating cytisinicline in nicotine e-cigarette users.

In November 2021, we announced that the FDA had completed their review and accepted the IND to investigate cytisinicline as a cessation treatment in this population. In June 2022, following NIH review of completed milestones, we announced that we were awarded the next grant funding from the NIDA, which we have used to conduct the ORCA-V1 Phase 2 clinical trial.

In June 2022, we announced the initiation of the ORCA-V1 Phase 2 clinical trial. ORCA-V1 will evaluate the efficacy and safety of 3 mg cytisinicline dosed three times daily compared to placebo in approximately 160 adult e-cigarette users at five clinical trial locations in the United States. Participants were randomized to receive cytisinicline or placebo for 12 weeks in combination with standard cessation behavioral support.

For the years ended December 31, 2023 and 2022 we incurred $1.2 million and $1.3 million, respectively, in qualifying R&D expenditures under the NIDA/NIH grant which has been recorded as a reduction in R&D expense. From inception of the grant award to December 31, 2023, we have received approximately $2.4 million in reimbursements from NIDA/NIH. As of December 31, 2023 we had $0.1 million in grant receivable related to the NIDA/NIH grant.

The grant award is expected to cover approximately half of the total ORCA-V1 clinical study costs. The Primary Investigators for the grant are our Chief Medical Officer, Dr. Cindy Jacobs, and Dr. Nancy Rigotti, Professor of Medicine at Harvard Medical School and Director, Tobacco Research and Treatment Center, Massachusetts General Hospital.

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

The components of intangible assets were as follows:

	December 31, 2023			December 31, 2022		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (1,920)	$ 1,197	$ 3,117	$ (1,699)	$ 1,418

For the year ended December 31, 2023 and 2022 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, 2023:

Year Ending December 31,	
2024	223
2025	223
2026	223
2027	223
Thereafter	305
Total	**$ 1,197**

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 that there were no indicators of impairment identified as of December 31, 2023.

6. LICENSE 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, certain cytisinicline trademarks 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 cytisinicline 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.

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma AD to acquire 75% of the outstanding shares of Extab Corporation for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisinicline by the FDA or the European Medicines Agency, or EMA. The fair value of the contingent consideration on the acquisition date was nil. The contingent consideration liability is measured at fair value in our financial statements,

As of December 31, 2023, the fair value of the contingent consideration was estimated to be $0.5 million (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated Financial Statements). We recognized a loss of $0.5 million for the year ended December 31, 2023.

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, 2023, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

7. FAIR VALUE MEASUREMENTS

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

ASC 820 “Fair Value Measurements and Disclosures” specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. In accordance with ASC 820, these inputs are summarized in the three broad levels 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 input that reflects 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

Money Market Securities

Money market securities are classified within Level 1 of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities.

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, 2023	Level 1	Level 2	Level 3	Total
Assets				
Money market securities (cash equivalents)	14,252	—	—	14,252
Restricted cash	50	—	—	50
Total assets	**$ 14,302**	**$ —**	**$ —**	**$ 14,302**
Liabilities				
Contingent consideration	—	—	528	528
Total liabilities	**$ —**	**$ —**	**$ 528**	**$ 528**

December 31, 2022	Level 1	Level 2	Level 3	Total
Assets				
Money market securities (cash equivalents)	22,756	—	—	22,756
Restricted cash	50	—	—	50
Total assets	**$ 22,806**	**$ —**	**$ —**	**$ 22,806**
Liabilities				
Contingent consideration	—	—	—	—
Total liabilities	**$ —**	**$ —**	**$ —**	**$ —**

Cash and cash equivalents (in thousands):

December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market securities	14,252	—	—	14,252
Total cash and cash equivalents	**$ 14,252**	**$ —**	**$ —**	**$ 14,252**
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	**$ 50**	**$ —**	**$ —**	**$ 50**

December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market securities	22,756	—	—	22,756
Total cash and cash equivalents	**$ 22,756**	**$ —**	**$ —**	**$ 22,756**
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	**$ 50**	**$ —**	**$ —**	**$ 50**

We only invest in A (or equivalent) rated securities. All securities included in cash and cash equivalents had maturities of 90 days or less at the time of purchase.

Fair Value of Long-Term Debt

Convertible Debt

The principal amount, carrying value and related estimated fair value of our convertible debt reported in the consolidated balance sheets as of December 31, 2023 and December 31, 2022 was as follows (in thousands). The aggregate fair value of the principal amount of the convertible debt is a Level 2 fair value measurement.

	December 31, 2023			December 31, 2022		
	Principal Amount	Carrying Value	Fair Value	Principal Amount	Carrying Value	Fair Value
December 2021 Convertible Debt	$ 15,000	$ 16,662	$ 16,652	$ 15,000	$ 16,071	$ 16,987

Fair Value of Sopharma Share Purchase Agreement Contingent Consideration

We determine the fair value of the contingent consideration using a probability based discounted cash flow model whereby we forecast the timing of the cash flow of the related future payment based on cytisnicline's current clinical development phase and the remaining requirements for regulatory approval. We then discount the expected payment amount to calculate the present value and then apply a probability of success in obtaining regulatory approval as of the valuation date. We evaluate the underlying projection used in determining the fair value each period and make updates as necessary.

The significant assumptions we use to value the contingent consideration are the forecasted timing of the future payment, the risk-adjusted discount rate and the probability of success which are all considered significant unobservable inputs, and as such, the liability is classified as a Level 3 measurement. The risk-adjusted discount rate is adjusted for credit risk.

An increase in the discount rate and decrease in the probability of success will result in a decrease in the fair value of the contingent consideration. Conversely, a decrease in the discount rate and increase in the probability of success will result in an increase in the fair value of the contingent consideration. At December 31, 2023 the risk adjusted discount rate was 38.0% and the probability of success was 67.2%. Adjustments to the fair value of the contingent liabilities, other than payments, are recorded as a gain or loss in the Consolidated Statements of Loss and Comprehensive Loss.

8. PROPERTY AND EQUIPMENT

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

	Cost	Accumulated Depreciation	Net Book Value
December 31, 2023			
Computer equipment	$ 114	$ 104	$ 10
Furniture and fixtures	28	28	—
Leasehold improvements	25	25	—
Computer software	77	74	3
Equipment under capital lease	12	12	—
Total property and equipment	$ 256	$ 243	$ 13

9. CONVERTIBLE DEBT

On December 22, 2021, we entered into a $25.0 million contingent convertible debt agreement, or Original Debt Agreement, with SVB, and SVB Innovation Credit Fund VIII, L.P., or, together with SVB, the Lenders. As part of the Original Debt Agreement, the Lenders funded $15.0 million in the form of convertible indebtedness, or Convertible Debt, at closing. On April 26, 2022, we entered into (i) a loan and security agreement, or Loan Agreement, with SVB for the remaining $10.0 million remaining in the Original Debt Agreement, pursuant to which SVB provided a commitment to extend term loans having an aggregate original principal amount of up to $10.0 million, or Term Loans, and (ii) a first amendment to the Original Debt Agreement, or the Amendment, and as amended by the Amendment, the Debt Agreement. The availability of Term Loans under the Loan Agreement expired on April 30, 2023, with no amounts drawn under the facility.

On May 15, 2023, we entered into a contingent convertible debt agreement, or Debt Agreement, with the Lenders, pursuant to which the Lenders provided term loans having an aggregate original principal amount of $16.6 million, or the Convertible Term Loan. The Convertible Debt under the Original Debt Agreement was refinanced as the Convertible Term Loan pursuant to the Debt Agreement. Our obligations under the Loan Agreement, Original Debt Agreement and Convertible Debt were satisfied in full and the Loan Agreement, Original Debt Agreement and Convertible Debt were terminated in connection with the entrance into the Debt Agreement and Convertible Term Loan.

The Convertible Term Loan matures on December 22, 2024; provided that (a) in the event we fail to receive written notice, or a Filing Communication, that the FDA has accepted for filing our NDA, with respect to cytisinicline for a smoking cessation indication, on or prior to July 31, 2024, the maturity date shall be August 1, 2024 or (b) in the event we receive a Filing Communication with respect to cytisinicline for a smoking cessation indication on or prior to August 14, 2024, but where such Filing Communication specifies any material deficiencies or material filing review issues with respect to such NDA, the maturity date shall be August 15, 2024; provided, further, that in the event we have submitted the NDA on or prior to June 30, 2024, the dates listed in (a) and (b) above shall be extended by one calendar month. Interest is calculated on the outstanding principal amount of the Convertible Term Loan at the aggregate of (a) a floating rate per annum equal to the greater of (i) 2.25% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears, and (b) 7.0% per annum, compounded monthly, which shall be payable on the earlier to occur of the maturity date and the date that the Convertible Term Loan is converted into our common stock.

Subject to certain terms and conditions, the Lenders may convert all or any part of the outstanding Convertible Term Loan principal and accrued and unpaid interest at any time prior to maturity into shares of our common stock at a conversion price equal to $9.34 per share, or the conversion price, subject to customary anti-dilution adjustments. Additionally, all outstanding Convertible Term Loan principal and accrued and unpaid interest will mandatorily convert into shares of our common stock, at the conversion price, on such date, if any, when the closing price per share of our common stock has been equal to or greater than $24.00 for thirty consecutive trading days prior to such date.

We have the right, or Call Right, at any time to repay and retire all (but not less than all) of the outstanding Convertible Term Loan and accrued and unpaid interest, if any, prior to its conversion by payment of a premium equal to 150% of the outstanding principal balance (including any compounded interest), plus accrued and unpaid interest; provided, however, that we may not exercise the Call Right at any time when the Liquidity Conditions (as defined in the Debt Agreement) are not satisfied.

Notwithstanding the foregoing, if we (x) elect to repay the Lenders and (y) in the twelve month period following such repayment, (i) enter into an agreement or similar commitment, binding or nonbinding, with any third party respecting an acquisition, and such acquisition is subsequently consummated, if the aggregate gross proceeds that would have been payable to the Lenders or, pursuant to an assignment, any designee thereof, or collectively, the Conversion Rights Holders, in connection with such acquisition had we not repaid the Convertible Term Loan and the Conversion Right Holders had exercised, in connection with such acquisition, the right to convert the Convertible Term Loan into shares of our common stock, then (z) we shall pay to the Lenders as an additional call price, the difference between such proceeds as would have been payable to the Conversion Right Holders in connection with such acquisition and the payment actually paid to the Lenders.

The Debt Agreement contains customary affirmative and restrictive covenants, including covenants regarding the incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, payment of taxes, maintenance of insurance, dispositions of property, mergers or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. The Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lenders may not engage in any short sales of, or other hedging transactions in, our common stock while any amounts are outstanding under the Debt Agreement. Our obligations under the Debt Agreement are secured by substantially all of our assets, other than intellectual property.

Under ASU 2020-06 for the Original Debt Agreement, the embedded conversion feature was not required to be bifurcated and recognized separately, as a result the convertible debt including the conversion feature has been recognized as a single unit of debt.

The debt issuance costs related to Convertible Debt under the Original Debt Agreement have been recognized against the single unit of debt and will be amortized into interest expense over the term of the Convertible Term Loan.

The debt refinancing in May 2023 was recognized as a debt modification under ASU 470-50 and the associated third-party issuance costs were expensed.

As of December 31, 2023, the Convertible Debt balance was comprised of the following:

	Year Ended December 31,	
	2023	2022
Convertible Debt Information		
Principal	$ 15,000	$ 15,000
Transaction Costs	(5)	(67)
Accrued paid-in-kind interest	2,311	1,138
Discount on modification of debt	(1,074)	—
Accretion of discount on modification of debt	430	—
	16,662	16,071

10. INCOME TAX

[a] We are a Delaware incorporated company subject to blended U.S. Federal and state statutory rates for December 31, 2023, 2022 and 2021 of 21%. 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.

U.S. and foreign components of income (loss) before income taxes were as follows (in thousands):

(In thousands)	2023	2022	2021
U.S.	$ (28,982)	$ (41,660)	$ (31,411)
Foreign	(833)	(690)	(1,741)
Income (loss) before income taxes	$ (29,815)	$ (42,350)	$ (33,152)

Income tax expense/(recovery) consisted of the following (in thousands):

(In thousands)	2023	2022	2021
Income tax recovery at statutory rates (at a rate of 21% for all years presented)	$ (6,261)	$ (8,894)	$ (6,962)
Expenses not deducted for tax purposes	477	299	224
Effect of tax rate changes on deferred tax assets and liabilities	(169)	(18)	17
Rate differential on foreign earnings	(36)	(26)	(77)
Research and development tax credits	(883)	(1,154)	(134)
Change in valuation allowance	7,686	10,464	7,544
Reassessment of previously recognized net operating losses	—	9	(620)
Adjustment to prior year research and development tax credits	(760)	(731)	—
Other	(54)	51	8
Income tax expense/(recovery)	$ —	$ —	$ —

[b] The tax effects of the temporary differences and carryforwards that give rise to deferred tax assets and liabilities are as follows (in thousands):

	2023	2022
Deferred tax assets		
Tax basis in excess of book value of assets	$ 899	$ 899
Net operating loss carryforwards	48,867	43,380
Research and development deductions and credits	10,716	8,942
Stock options	1,134	1,042
Capitalized R&D expenses	11,528	11,342
Other	434	334
Total deferred tax assets	73,578	65,939
Valuation allowance	(73,232)	(65,546)
Net deferred tax assets	346	393
Deferred tax liabilities		
Right-of-use asset	(91)	(91)
Other	(255)	(302)
Total deferred tax liabilities	(346)	(393)
Net deferred tax liabilities	—	—

A valuation allowance is recorded when it is more likely than not that all or some portion of the deferred tax assets, or DTAs, will not be realized. Management assesses the need for a valuation allowance against the deferred tax assets when considering both positive and negative evidence related to whether it is more likely than not that the deferred tax assets will be realized. In evaluating the ability to recover the deferred tax assets within the jurisdiction from which they arise, all available positive and negative evidence is considered, including scheduled reversals of deferred tax liabilities, projected future growth, tax-planning strategies, and results of recent operations.

Due to the uncertainty surrounding the realization of deductible tax attributes in future tax returns, we have recorded a valuation allowance for deferred tax assets of $73.2 million to reduce the DTAs to zero as of December 31, 2023. The valuation allowance increased by approximately $7.7 million during the year ended December 31, 2023. The amount of the DTA considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

We have total net operating loss carryforwards for federal tax purposes of approximately $90.2 million ($66.1 million—2022) as of December 31, 2023, some of which will begin to expire in 2029. Approximately $80.2 million of the federal net operating losses will carryforward indefinitely. Federal net operating losses generated after January 1, 2018 were originally available to offset 80% of taxable income for any given future tax year and will be carried forward indefinitely. We have research and development tax credit carryforwards of approximately $4.0 million ($2.3 million—2022) as of December 31, 2023, which will begin to expire in 2037. The operating loss carryforwards and research and development tax credits may be limited due to a change in control in our ownership as defined by the Internal Revenue Code Section 382. Any future changes in our ownership may limit the use of such carryforward benefits.

Our effective income tax rate for the periods presented differ from the statutory rate of 21% primarily due to current year net losses and the full valuation allowance on the U.S. deferred tax assets. We file income tax returns in the United States, Canada, and the United Kingdom, or U.K. At December 31, 2023, we have Canadian non-capital loss carryforwards of $107.0 million ($110.0 million—2022) and research tax credits of $2.7 million ($2.7 million —2022), both of which will expire in 2042. In addition, we have unclaimed tax deductions of approximately $15.8 million related to scientific research and experimental development expenditures available to carry forward indefinitely to reduce Canadian taxable income of future years. The U.K. net operating loss carryforwards of $4.0 million (2022—$3.4 million) will carry forward indefinitely. As of December 31, 2023 and 2022, there are no tax penalties or accrued interest recorded in the financial statements.

[c] A reconciliation of the unrecognized tax benefits of uncertain tax positions for the year ended December 31, 2023 is as follows (in thousands):

	Year ended December 31,		
	2023	2022	2021
Gross unrecognzed tax benefits at January 1	$ 761	$ 761	$ 767
Additions (reductions) from tax positions taken in prior years	—	—	(6)
Additions (reductions) from tax positions taken in the current year	—	—	—
Tax settlements	—	—	—
Gross unrecognzed tax benefits at December 31	$ 761	$ 761	$ 761

As of December 31, 2023, unrecognized benefits of approximately $0.8 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, 2023 and December 31, 2022 we had no accrued interest and penalties related to income taxes.

We are subject to taxes in Canada, the U.K. and the United States until the applicable statute of limitations expires. However, in Canada and the United States, all tax years remain subject to examination due to the carryforward of unutilized NOLs and tax credits. Tax audits by their very nature are often complex and can require several years to complete. To our knowledge, we are not currently under examination by any taxing authorities.

Tax Jurisdiction	Years open to examination
Canada	2019 to 2023
United Kingdom	2017 to 2023
US	2020 to 2023

11. COMMON STOCK

[a] Authorized

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

[b] Issued and outstanding shares

May 2021 Public Offering

On May 27, 2021, we completed an underwritten public offering of our securities, pursuant to which we sold an aggregate of 3,285,714 shares of our common stock, including 428,571 shares subject to the underwriter's option to purchase additional shares, or the May 2021 Shares. The May 2021 Shares were sold at the public offering price of $7.00 per share.

The underwritten public offering raised total gross proceeds of approximately $23.0 million and after deducting approximately $1.7 million in underwriting discounts and commissions and offering expenses, we received net proceeds of approximately $21.3 million. The underwriting discounts and commissions and offering expenses have been charged against the gross proceeds.

At-the-Market Sales Agreement

On December 21, 2021, we entered into an At-the-Market Offering Sales Agreement, or ATM, with Virtu Americas, LLC, as sales agent, pursuant to which from December 21, 2021 through December 31, 2023, we offered and sold an aggregate of 200,000 shares of our common stock. These aggregate sales resulted in gross proceeds to us of approximately $1.5 million. During the year ended December 31, 2023, we did not sell any shares of our common stock pursuant to the ATM. The ATM was subsequently terminated on February 29, 2024 and no further sales of our common stock will be made pursuant to the ATM.

November 2022 Private Placement

In November 2022, we entered into subscription agreements with certain accredited investors pursuant to which we sold to the purchasers in a private placement transaction approximately 4,093,141 units at a purchase price of $4.625 per unit, with each unit consisting of two shares of common stock and a common stock purchase warrant to purchase one share of common stock, or the November 2022 Warrants.

The November 2022 Warrants are exercisable at a price per share of common stock of $4.50, subject to adjustment. The November 2022 Warrants are exercisable beginning on the six-month anniversary of the initial closing date of the private placement offering, May 18, 2023, or the Initial Exercise Date, and will expire on the seven year anniversary of the initial closing date of the private placement offering, or November 18, 2029. The November 2022 Warrants cannot be exercised by a warrant holder if, after giving effect thereto, such warrant holder would beneficially own more than 19.99% of our outstanding common stock. Additionally, subject to certain exceptions, if, after the Initial Exercise Date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the November 2022 Measurement Period, which November 2022 Measurement Period commenced on November 18, 2022, 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 November 2022 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 November 2022 Warrants then outstanding.

We received approximately $17.9 million in net proceeds from the private placement after deducting placement agent expenses and commissions and offering expenses.

May 2023 Registered Direct Offering

In May 2023, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 3,000,000 shares of common stock at a price of $5.50 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3, including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated May 25, 2023.

The registered direct offering raised total gross proceeds of approximately $16.5 million, and after deducting approximately $1.2 million in placement agent fees and offering expenses, we received net proceeds of approximately $15.3 million.

Equity Award Issuances and Settlements

During the year ended December 31, 2023, we did not issue any shares of common stock to satisfy stock option exercises and issued 139,750 shares of common stock to satisfy restricted stock unit settlements. During the year ended December 31, 2022 we did not issue any shares of common to satisfy stock option exercises and 26,625 shares of common stock to satisfy restricted stock unit settlements for the year ended.

[c] Stock options

2023 Non-Employee Director Equity Incentive Plan

As of December 31, 2023, we had reserved, pursuant to the 2023 Non-Employee Director Equity Incentive Plan, or the 2023 Non-Employee Director Plan, 300,000 shares of common stock for issuance upon exercise of stock options by non-employee directors, of which 132,750 shares were reserved for options currently outstanding and 167,250 shares were available for future equity grants.

Under the 2023 Non-Employee Director Plan, we may grant options to purchase shares of our common stock or restricted stock units to our non-employee directors. The exercise price of the options is determined by our Board but will be at least equal to the fair value of the shares of common stock at the grant date. The options vest in accordance with terms as determined by our Board, typically over one to three years. The expiry date for each option is set by our Board with a maximum expiry date of ten years from the date of grant. In addition, the 2023 Non-Employee Director Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control.

2018 Equity Incentive Plan

As of December 31, 2023, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 1,722,253 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 1,180,905 were reserved for options currently outstanding, 507,875 for restricted stock units currently outstanding, and 33,473 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, or Board, but will be at least equal to the fair value of the shares of common stock at the grant date. The options vest in accordance with terms as determined by our Board, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our Board. The expiry date for each option is set by our Board 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.

New Employee Inducement Grants

We grant stock options as a material inducement to new employees for entering into employment agreements with us in accordance with Nasdaq Listing Rule 5635(c)(4). The stock options approved under the inducement grant were issued pursuant to a stock option agreement on terms substantially similar to our 2018 Equity Incentive Plan. 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. 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. For the year ended December 31, 2023 we granted 40,000 stock options to new employees. As of December 31, 2023, 135,000 stock options granted as new employee inducement grants were outstanding.

2017 Equity Incentive Plan

As of December 31, 2023, we had reserved, pursuant to the 2017 Equity Incentive Plan, or the 2017 Plan, 13,156 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 shares of common stock or restricted stock units to our employees, directors, officers and consultants. The exercise price of the options was determined by our Board but was at least equal to the fair value of the shares of common stock at the grant date. The options vest in accordance with terms as determined by our Board, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our Board. The expiry date for each option was set by our Board 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, 2023, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 169 common shares for issuance upon exercise of stock options, currently outstanding, by employees, directors, officers and consultants of ours.

Under the 2010 Plan we granted options to purchase shares of common stock 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 shares of common stock at the grant date. The options vest in accordance with terms as determined by our Board, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our Board. The expiry date for each option is set by our Board 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 2017 Merger Agreement between Achieve Life Sciences, Inc. and OncoGenex Pharmaceuticals. 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 for grants with an expected life of five years or more. For grants with an expected life of less than five years, the expected volatility was calculated based on the historical volatility of the shares of our common stock. 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:

	2023	2022
Risk-free interest rates	3.60%	1.65%
Expected dividend yield	0%	0%
Expected life	5.75 years	5.80 years
Expected volatility	115.19%	122.80%
Forfeiture rate	0%	0%

The weighted average fair value of stock options granted during the year ended December 31, 2023 was $4.40.

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,	
	2023	2022
Research and development	$ 1,122	$ 1,117
General and administrative	2,317	2,153
Total stock-based compensation	$ 3,439	$ 3,270

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, 2023	**822,515**	$ 18.57
Granted	639,500	5.23
Expired	(35)	25,555.20
Balance, December 31, 2023	**1,461,980**	**$ 12.12**

The following table summarizes information about stock options outstanding at December 31, 2023 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)
$4.53 - $4.72	25,000	$ 4.53	9.20
$4.73 - $4.99	409,750	4.90	9.07
$5.00 - $5.99	156,750	5.88	9.17
$6.00 - $7.22	122,200	6.42	8.78
$7.23 - $7.89	45,000	7.38	7.82
$7.90 - $8.43	226,250	8.26	8.01
$8.44 - $10.78	114,750	10.23	6.90
$10.79 - $12.60	80,530	11.26	6.16
$12.61 - $20.74	232,750	13.09	7.07
$20.75 - $25,938.00	49,000	134.00	4.70
	1,461,980	**$ 12.12**	**8.06**

(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)
$4.53 - $4.72	—	—	—
$4.73 - $4.99	—	—	—
$5.00 - $5.99	41,064	5.85	9.14
$6.00 - $7.22	39,263	6.88	8.14
$7.23 - $7.89	24,270	7.38	7.80
$7.90 - $8.43	144,549	8.26	8.01
$8.44 - $10.78	114,750	10.23	6.90
$10.79 - $12.60	78,507	11.26	6.15
$12.61 - $20.74	169,715	13.09	7.07
$20.75 - $25,938.00	49,000	134.00	4.70
	661,118	**$ 19.25**	**7.18**

As at December 31, 2023, and December 31, 2022, the total unrecognized compensation expense related to stock options granted was $3.4 million and $3.2 million, respectively, each of which is expected to be recognized into expense over a period of approximately 1.69 years.

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. No options were exercised for the years ended December 31, 2023, 2022 and 2021. At December 31, 2023, 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, 2023, 2022 and 2021, $0.9 million, $1.1 million and $0.4 million, respectively, of stock based compensation expense was recognized related to these awards.

The following table summarizes our restricted stock unit award activity during the year ended December 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, January 1, 2023	**252,875**	**$ 8.77**
Granted	394,750	4.90
Released	(139,750)	9.18
Balance, December 31, 2023	**507,875**	**$ 5.65**

As of December 31, 2023, we had approximately $0.3 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 0.07 years.

[e] Employee Stock Purchase Plan

Our board of directors and stockholders approved the 2017 Employee Stock Purchase Plan, or ESPP, in August 2017. Contributions are made by eligible employees, subject to certain limits defined in the ESPP. The maximum number of shares authorized to be purchased under the ESPP is 0.3 million shares. All shares purchased under the ESPP are new share issuances. For the year ended December 31, 2023 no shares were purchased under the ESPP. For the year ended December 31, 2022, 28,892 shares were purchased under the ESPP.

[f] Non-employee options and restricted stock units

We recognize non-employee stock-based compensation expense over the period of expected service by the non-employee. As the service is performed, we are required to update our valuation assumptions, re-measure unvested options and restricted stock units and record the stock-based compensation using the valuation as of the vesting date. This differs from the accounting for employee awards where the fair value is determined at the grant date and is not subsequently adjusted. This re-measurement may result in higher or lower stock-based compensation expense in the consolidated statements of loss and comprehensive loss. As such, changes in the market price of our stock could materially change the value of an option or restricted stock unit and the resulting stock-based compensation expense.

[g] Common Stock Warrants

The following is a summary of outstanding warrants to purchase common stock at December 31, 2023:

	Total Outstanding and Exercisable		Exercise price per Share	Expiration Date
(1) Warrants issued in May 2019 financing	60,000	$	90.0000	May 2025
(2) Warrants issued in December 2019 financing	510,924	$	2.3100	December 2024
(3) Warrants issued in April 2020 financing	182,461	$	7.2400	April 2025
(4) Warrants issued in April 2020 financing	24,375	$	7.3200	April 2025
(5) Warrants issued in April 2020 financing	25,270	$	7.5900	April 2025
(6) Pre-Funded Warrants issued in August 2020 financing	142,857	$	0.0010	*
(7) Warrants issued in December 2020 financing	50,000	$	8.7500	December 2025
(8) Warrants issued in November 2022 financing	4,093,141	$	4.5000	November 2029

* The pre-funded warrants do not have an expiration date.

The agreements governing the above warrants include the following terms:

- certain warrants have exercise prices which are subject to adjustment for certain events, including the issuance of stock dividends on our common stock and, in certain instances, the issuance of our common stock or instruments convertible into our common stock at a price per share less than the exercise price of the respective warrants (specifically those issued under the December 2019 Public Offering and November 2022 Private Placement);

•warrant holders may exercise the warrants through a cashless exercise if, and only if, we do not have an effective registration statement then available for the issuance of the shares of our common stock. If an effective registration statement is available for the issuance of our common stock a holder may only exercise the warrants through a cash exercise;
•the exercise price and the number and type of securities purchasable upon exercise of the warrants are subject to adjustment upon certain corporate events, including certain combinations, consolidations, liquidations, mergers, recapitalizations, reclassifications, reorganizations, stock dividends and stock splits, a sale of all or substantially all of our assets and certain other events; and
•in the event of an "extraordinary transaction" or a "fundamental transaction" (as such terms are defined in the respective warrant agreements), generally including any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, or reclassification of its common stock, in which the successor entity (as defined in the respective warrant agreements) that assumes the successor entity is not a publicly traded company, the Company or any successor entity will pay the warrant holder, at such holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the extraordinary transaction or fundamental transaction, an amount of cash equal to the value of such holder's warrants as determined in accordance with the Black Scholes option pricing model and the terms of the respective warrant agreement. In some circumstances, we or successor entity may be obligated to make such payments regardless of whether the successor entity that assumes the warrants is a publicly traded company.

For the year ended December 31, 2023, warrants to purchase 98,333 shares, issued in the December 2019 financing, were exercised at a per unit price of $2.31, for proceeds of $0.2 million. For the year ended December 31, 2022, warrants to purchase 3,709 shares, issued in the December 2019 financing, were exercised at a per unit price of $6.60, for proceeds of $24,480. As of December 31, 2023, all of our outstanding warrants are classified as equity.

[h] 401(k) Plan

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

[i] 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,		
	2023	2022	2021
Numerator			
Net loss	$ (29,815)	$ (42,350)	$ (33,152)
Denominator			
Weighted average number of common shares outstanding	19,827,354	10,593,034	8,119,836
Basic and diluted net loss per common share	$ (1.50)	$ (4.00)	$ (4.08)

As of December 31, 2023, a total of 7,058,883 million shares, consisting of warrants to purchase 5,089,028 shares, options exercisable for 1,461,980 shares and 507,875 restricted stock units have not been included in the calculation of potential common shares as their effect on diluted per share amounts would have been anti-dilutive. Additionally, the outstanding Convertible Debt due December 2024 is included in the calculation of diluted per share amounts only if its inclusion is dilutive for periods during which the notes were outstanding. As of December 31, 2023, the outstanding Convertible Debt was not included in the calculation of diluted per share amounts as its effect would have been anti-dilutive.

12. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of December 31, 2023 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Vancouver office operating lease	$ 74	$ 68	$ 6	$ —	$ —
Total	$ 74	$ 68	$ 6	$ —	$ —

Leases

We have an operating lease for our corporate office.

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

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

Vancouver Lease Arrangements

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. On December 16, 2022, we entered into an agreement to extend the lease for another two-year term, which commenced on February 1, 2023. 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):

2024		68
2025		6
Total	**$**	**74**

Consolidated rent and operating expense relating to both the Vancouver, Canada and Seattle, Washington offices for years ended December 31, 2023, 2022 and 2021 was $0.1 million, $0.1 million and $0.1 million, respectively.

Other information related to leases was as follows:

	Year Ended December 31,	
	2023	**2022**
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 57	$ 59
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	120
Weighted Average Remaining Lease Term		
Operating leases	1.08 years	2.08 years
Weighted Average Discount Rate		
Operating leases	8.98%	8.98%

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, 2023.

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.

13. SUBSEQUENT EVENTS

February 2024 Registered Direct Offering and Concurrent Private Placement

In February 2024, we entered into a securities purchase agreement with certain purchasers, pursuant to which we sold 13,086,151 shares of common stock at a price of $4.585 per share in a registered direct offering. The offering of the shares was made pursuant to our shelf registration statement on Form S-3, including the prospectus dated January 5, 2022 contained therein, and the prospectus supplement dated February 29, 2024.

In a concurrent private placement, we issued unregistered warrants to purchase up to 13,086,151 shares of common stock at an exercise price of $4.906 per share (provided, however, that the purchaser may elect to exercise the warrants for pre-funded warrants in lieu of shares of common stock at an exercise price of $4.906, minus $0.001, the exercise price of each pre-funded warrant). These warrants will be immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof, and will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following our public disclosure of the acceptance of an NDA for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence.

The registered direct offering raised total gross proceeds of approximately $60.0 million, and after deducting approximately $3.8 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.2 million.

Convertible Debt

On February 26, 2024, we entered into a non-binding term sheet, or the Term Sheet, for an extension of the maturity date for the term loans outstanding pursuant to our Debt Agreement with Lenders. There is no guarantee that we will be able to enter into a definitive agreement with the Lenders on the terms provided in the Term Sheet or any at all. (See “Item 1A. Risk Factors - Risks Related to Our Financial Condition and Capital Requirements").

At-the-Market Sales Agreement

On February 29, 2024, we terminated the ATM agreement with Virtu and no further sales of our common stock will be made pursuant to the ATM.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

We carried out an evaluation, under the supervision and with the participation of our management, including the principal executive officer and the principal financial officer, of the effectiveness of the design and operation of the disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2023.

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, 2023 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, 2023, 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, 2023.

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

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of December 31, 2023, and is incorporated by reference into this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of December 31, 2023, and is incorporated by reference into this Annual Report on Form 10-K**.**

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, 2023:

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders[1]	1,834,855	$ 7.88	200,723
Equity compensation plans not approved by security holders[2]	135,000	$ 6.21	—
Total	1,969,855	$ 14.09	200,723

(1)As of December 31, 2023, we maintained the following equity compensation plans, which were approved by security holders: (a) the 2010 Performance Incentive Plan, (b) the 2017 Equity Incentive Plan, (c) the 2018 Equity Incentive Plan and (d) the 2023 Non-Employee Director Equity Incentive Plan.

(2)Stock options granted as an inducement to new employees for entering into employment agreements with us in accordance with Nasdaq Listing Rule 5635(c)(4).

The remaining information required by this Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of December 31, 2023, and is incorporated by reference into this Annual Report on Form 10-K.

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

The information required by this Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of December 31, 2023, and is incorporated by reference into this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of December 31, 2023, and is incorporated by reference into this Annual Report on Form 10-K.

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	
3.1	Third Amended and Restated Certificate of Incorporation, filed June 8, 2023	8-K	033-80623	3.1	June 9, 2023	
3.2	Certificate of Designation of Preferences, Rights and Limitations, with respect to the Series B Convertible Preferred Stock, filed	8-K	033-80623	3.1	December 20, 2019	
3.3	Sixth Amended and Restated Bylaws	8-K	033-80623	3.1	January 5, 2017	
3.4	Amendment to Sixth Amended and Restated Bylaws	10-Q	033-80623	3.1	November 7, 2018	
4.1	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934	10-K	033-80623	4.12	March 13, 2020	
4.2	Specimen Certificate of Common Stock	10-Q	000-21243	4.1	November 10, 2008	
4.3	Form of Preferred Stock Certificate	8-K	033-80623	4.2	June 20, 2018	
4.4	Form of Common Stock Purchase Warrant (October 2018 Private Placement)	8-K	033-80623	4.1	October 1, 2018	
4.5	Form of Warrant (May 2019)	8-K	033-80623	4.1	June 3, 2019	
4.6	Form of Common Stock Purchase Warrant (December 2019 Offering)	8-K	033-80623	4.1	December 20, 2019	
4.7	Form of Common Stock Purchase Warrant (April 2020)	8-K	033-80623	4.1	April 30, 2020	
4.8	Form of Pre-Funded Warrant (August 2020)	8-K	033-80623	4.1	August 4, 2020	
4.9	Form of Underwriter's Warrant	S-1	333-250074	4.11	November 30, 2020	
4.10	Form of Common Stock Purchase Warrant (November 2022)	8-K	033-80623	4.1	November 18, 2022	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
4.11	Form of Common Stock Warrant (March 2023)	8-K	033-80623	4.1	February 29, 2024	
4.12	Form of Registration Rights Agreement	8-K	033-80623	10.2	November 18, 2022	
4.13	Registration Rights Agreement, dated May 15, 2023, by and among Achieve Life Sciences, Inc., Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P. and SVB Innovation Credit Fund VIII-A, L.P.	8-K	033-80623	10.2	May 17, 2023	
10.1	Form of OncoGenex Pharmaceuticals, Inc. 2010 Stock Option Agreement††	8-K	033-80623	10.1	June 14, 2010	
10.2	Form of OncoGenex Pharmaceuticals, Inc. 2010 Restricted Stock Unit Agreement††	10-Q	033-80623	10.2	November 3, 2011	
10.3	OncoGenex Pharmaceuticals, Inc. 2010 Performance Incentive Plan, as amended and restated††	DEF 14A	033-80623	Appendix A	April 16, 2015	
10.4	Achieve Life Sciences 2017 Equity Incentive Plan††	DEF 14A	033-80623	Appendix A	September 21, 2017	
10.5	Form of Achieve Life Sciences Stock Option Agreement††	10-Q	033-80623	10.7b	March 1, 2018	
10.6	Form of Achieve Life Sciences Restricted Stock Unit Agreement††	10-Q	033-80623	10.7c	March 1, 2018	
10.7	Achieve Life Sciences 2017 Employee Stock Purchase Plan††	DEF 14A	033-80623	Appendix B	September 21, 2017	
10.8	Achieve Life Sciences 2018 Equity Incentive Plan, as amended, and forms of award agreements thereunder††	10-K	033-80623	10.8	March 16, 2023	
10.9	Achieve Life Sciences, Inc. 2023 Non-Employee Director Equity Incentive Plan, and forms of award agreements thereunder	DEF 14A	033-80623	Appendix B	April 28, 2023	
10.10	Form of Indemnification Agreement for Officers and Directors of the Company					X
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 OncoGenex Pharmaceuticals, Inc. and John Bencich††	10-Q	033-80623	10.1	November 10, 2016	
10.13	Employment Agreement between the Company and Richard Stewart, executed May 22, 2018 ††	8-K	033-80623	10.1	May 23, 2018	
10.14	Amended and Restated Employment Agreement, dated September 28, 2020, by	10-Q	033-80623	10.3	November 12, 2020	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
	and between Achieve Life Sciences, Inc. and John Bencich ††					
10.15	Amended and Restated Employment Agreement, dated September 27, 2022, by and between Achieve Life Sciences, Inc. and Cindy Jacobs ††	10-K	033-80623	10.26	March 16, 2023	
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	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	
10.18	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	
10.19	Variation of Contract, by and between Sopharma AD and Extab Corporation, dated May 14, 2015*	S-4/A	333-216961	10.24	May 3, 2017	
10.20	Technical and Quality Agreement, by and between Sopharma AD and Extab Corporation, dated May 14, 2015*	S-4/A	333-216961	10.25	May 3, 2017	
10.21	Share Purchase Agreement, by and between Sopharma AD and Achieve Life Sciences, Inc., dated May 14, 2015*					X
10.22	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	
10.23	Amendment One to License of Technology, dated January 22, 2018, by and between Achieve Life Science, Inc., and the University of Bristol*	10-Q/A	033-80623	10.1	May 23, 2018	
10.24	Amended and Restated Commercial Agreement on Supply of Pharmaceutical Products, dated July 28, 2017, by and between Achieve Life Science, Inc., and Sopharma AD*	10-Q	033-80623	10.1	November 9, 2017	
10.25	Letter of Variation, dated September 28, 2020, by and between Achieve Pharma UK Limited and Richard Stewart††	10-Q	033-80623	10.1	November 12, 2020	
10.26	Cooperation Agreement, dated March 1, 2023, by and among Achieve Life Sciences, Inc., Dialectic Capital Management, LP and the other parties set forth on the signature pages thereto	8-K	033-80623	10.1	March 6, 2023	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.27	Amendment to Cooperation Agreement, dated March 21, 2023, by and among Achieve Life Sciences, Inc., Dialectic Capital Management, LP and the other parties set forth on the signature pages thereto	8-K	033-80623	10.1	March 23, 2023	
10.28	2023 Convertible Contingent Debt Agreement, dated May 15, 2023, by and among Achieve Life Sciences, Inc., Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P. and SVB Innovation Credit Fund VIII-A, L.P.	8-K	033-80623	10.1	May 17, 2023	
10.29	Securities Purchase Agreement, dated as of February 28, 2024, by and among Achieve Life Sciences, Inc. and the purchasers identified on the signature pages thereto	8-K	033-80623	10.1	February 29, 2024	
10.30	Office Lease by and between 0846869 B.C. Ltd. and Achieve Life Sciences Technologies Inc., commencing February 1, 2019	10-K	033-80623	10.25	March, 14, 2019	
10.31	Lease Extension Agreement, dated December 16, 2022, by and between 0846869 B.C. Ltd. and Achieve Life Sciences Technologies Inc.	10-K	033-80623	10.22	March 16, 2023	
10.32	Office Lease by and between Regus Management Group, LLC and Achieve Life Sciences, Inc., commencing March 1, 2024					X
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)					
31.1	Certification of Chief Executive Officer (Principal Executive Officer and 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 (Principal Executive Officer and Financial Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**					X
97.0	Compensation Recovery Policy					X

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover page formatted as Inline XBRL and contained in Exhibit 101					X

† Schedules and similar attachments to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish supplementally a copy of any omitted schedule or similar attachment to the SEC upon request.
†† Indicates management contract or compensatory plan or arrangement.
* The Company has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.
** The certifications attached as Exhibits 32.1 and 32.2 accompany to this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 16. FORM 10-K SUMMARY

None.

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 28, 2024

By: /s/ JOHN BENCICH
John Bencich
Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John Bencich and Richard Stewart, 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/ JOHN BENCICH John Bencich	Chief Executive Officer and Director (Principal Executive Officer and Financial Officer)	Date: March 28, 2024
By: /s/ JERRY WAN Jerry Wan	Senior Director of Accounting Operations (Principal Accounting Officer)	Date: March 28, 2024
By: /s/ RICHARD STEWART Richard Stewart	Executive Chairman and Director	Date: March 28, 2024
By: /s/ CINDY JACOBS Cindy Jacobs	President, Chief Medical Officer and Director	Date: March 28, 2024
By: /s/ BRIDGET MARTELL Bridget Martell	Director	Date: March 28, 2024
By: /s/ VAUGHN HIMES Vaughn Himes	Director	Date: March 28, 2024
By: /s/ STUART DUTY Stuart Duty	Director	Date: March 28, 2024
By: /s/ THOMAS KING Thomas King	Director	Date: March 28, 2024
By: /s/ THOMAS SELLIG Thomas Sellig	Director	Date: March 28, 2024

EXHIBIT 10.10

INDEMNIFICATION AGREEMENT

This INDEMNIFICATION AGREEMENT ("Agreement") is made as of □, between ACHIEVE LIFE SCIENCES, INC., a Delaware corporation (the "Company"), and _____ ("Indemnitee"), an officer and/or member of the Board of Directors of the Company.

WHEREAS, the Company desires the benefits of having Indemnitee serve as an officer and/or director secure in the knowledge that expenses, liability and losses incurred by Indemnitee in Indemnitee's good faith service to the Company will be borne by the Company or its successors and assigns in accordance with applicable law; and

WHEREAS, the Company desires that Indemnitee resist and defend against what Indemnitee may consider to be unjustified investigations, claims, actions, suits and proceedings which have arisen or may arise in the future as a result of Indemnitee's service to the Company notwithstanding that conditions in the insurance markets may make directors' and officers' liability insurance coverage unavailable or available only at premium levels which the Company may deem inappropriate to pay; and

WHEREAS, the parties believe it appropriate to memorialize and reaffirm the Company's indemnification obligations to Indemnitee and, in addition, set forth the indemnification agreements contained herein;

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties agree as follows:

1.**Indemnification.** Indemnitee shall be indemnified and held harmless by the Company to the fullest extent permitted by its Certificate of Incorporation, Bylaws and applicable law, as the same exists or may hereafter be amended, against all expenses, liability and loss (including attorneys' fees, judgments, fines, and amounts paid or to be paid in any settlement approved in advance by the Company, such approval not to be unreasonably withheld) (collectively, "Indemnifiable Expenses") actually reasonably incurred or suffered by Indemnitee in connection with any present or future threatened, pending or contemplated investigation, claim, action, suit or proceeding, whether civil, criminal, administrative or investigative (collectively, "Indemnifiable Litigation"), (i) to which Indemnitee is or was a party or is threatened to be made a party by reason of any action or inaction in Indemnitee's capacity as a director or officer of the Company, or (ii) with respect to which Indemnitee is otherwise involved by reason of the fact that Indemnitee is or was serving as a director, officer, employee or agent of the Company, or of any subsidiary or division, or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise. Notwithstanding the foregoing, Indemnitee shall have no right to indemnification for expenses and the payment of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 16(b) of the Securities and Exchange Act of 1934, as amended.

2.**Interim Expenses.** The Company agrees to pay Indemnifiable Expenses incurred by Indemnitee in connection with any Indemnifiable Litigation in advance of the final disposition thereof,

provided that the Company has received an undertaking by or on behalf of Indemnitee, substantially in the form attached hereto as Exhibit A, to repay the amount so advanced to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company under this Agreement or otherwise. The advances to be made hereunder shall be paid by the Company to Indemnitee within twenty (20) days following delivery of a written request therefor by Indemnitee to the Company.

3.**Procedure for Making Demand.** Indemnitee shall, as a condition precedent to his right to be indemnified under this Agreement, give the Company notice in writing as soon as practicable of any claim made against Indemnitee for which indemnification will or could be sought under this Agreement. Notice to the Company shall be directed to the Chief Executive Officer of the Company at the address set forth in Section 10 hereof (or such other address as the Company shall designate in writing to Indemnitee). Notice shall be deemed received three business days after the date postmarked and sent by certified or registered mail, properly addressed; otherwise notice shall be deemed received when such notice shall actually be received by the Company. In addition, Indemnitee shall give the Company such information and cooperation as it may reasonably require and as shall be within Indemnitee's power. Any indemnification provided for in Section 1 shall be made no later than forty-five (45) days after receipt of the written request of Indemnitee.

4.**Failure to Indemnify.**

(a)If a claim under this Agreement, or any statute, or under any provision of the Company's Second Amended and Restated Certificate of Incorporation or Bylaws providing for indemnification, is not paid in full by the Company, within forty-five (45) days after a written request for payment thereof has been received by the Company, Indemnitee may, but need not, at any time thereafter bring an action against the Company to recover the unpaid amount of the claim and, subject to Section 11 of this Agreement, if successful in whole or in part, Indemnitee shall also be entitled to be paid for the expense (including attorneys' fees) of bringing such action.

(b)It shall be a defense to such action (other than an action brought to enforce a claim for expenses incurred in connection with any action, suit or proceeding in advance of its final disposition) that Indemnitee has not met the standard of conduct which make it permissible under applicable law for the Company to indemnify Indemnitee for the amount claimed, but the burden of proving such defense shall be on the Company and Indemnitee shall be entitled to receive interim payments of interim expenses pursuant to Section 2 hereof unless and until such defense may be finally adjudicated by court order or judgment from which no further right of appeal exists. It is the parties' intention that if the Company contests Indemnitee's right to indemnification, the question of Indemnitee's right to indemnification shall be for the court to decide, and neither the failure of the Company (including its board of directors, independent legal counsel, or its stockholders) to have made a determination that indemnification of Indemnitee is proper in the circumstances because Indemnitee has met the applicable standard of conduct required by applicable law, nor an actual determination by the Company (including its board of directors, any committee or subgroup of the board of directors, independent legal counsel, or its stockholders) that Indemnitee has not met such applicable standard of conduct, shall create a presumption that Indemnitee has or has not met the applicable standard of conduct.

5.**Notice to Insurers.** If, at the time of the receipt of a notice of a claim pursuant to Section 3 thereof, the Company has director and/or officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with

the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

6.**Retention of Counsel.** In the event that the Company shall be obligated to pay Indemnifiable Expenses as a result of any proceeding against Indemnitee, the Company, if appropriate, shall be entitled to assume the defense of such proceeding, with counsel approved by Indemnitee, which approval shall not be unreasonably withheld, upon the delivery to Indemnitee of written notice of its election to do so. After delivery of such notice, approval of such counsel by Indemnitee and the retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees of counsel subsequently incurred by that Indemnitee with respect to that same proceeding, provided that (i) Indemnitee shall have the right to employ his or her counsel in any such proceeding at Indemnitee's expense, and (ii) if (A) the employment of counsel by Indemnitee has been previously authorized by the Company, (B) Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and Indemnitee in the conduct of any such defense, or (C) the Company shall not, in fact, have employed counsel to assume defense of such proceeding, then the fees and expenses of Indemnitee's counsel shall be at the expense of the Company.

7.**Successors.** This Agreement establishes contract rights which shall be binding upon, and shall inure to the benefit of, the successors, assigns, heirs and legal representatives of the parties hereto.

8.**Mutual Acknowledgment.** Both the Company and Indemnitee acknowledge that in certain instances, Federal law or applicable public policy may prohibit the Company from indemnifying its directors and officers under this Agreement or otherwise. Indemnitee understands and acknowledges that the Company may be required in the future to undertake to the Securities and Exchange Commission to submit the question of indemnification to a court in certain circumstances for a determination of the Company's right under public policy to indemnify Indemnitee, and, in that event, the Indemnitee's rights and the Company's obligations hereunder shall be subject to that determination.

9.**Contract Rights Not Exclusive.** The contract rights conferred by this Agreement shall be in addition to, but not exclusive of, any other right which Indemnitee may have or may hereafter acquire under any statute, provision of the Company's Second Amended and Restated Certificate of Incorporation or Bylaws, agreement, vote of shareholders or disinterested directors, or otherwise.

10.**Indemnitee's Obligations.** The Indemnitee shall promptly advise the Company in writing of the institution of any investigation, claim, action, suit or proceeding which is or may be subject to this Agreement and keep the Company generally informed of, and consult with the Company with respect to, the status of any such investigation, claim, action, suit or proceeding. Notices to the Company shall be directed to Achieve Life Sciences, Inc., 1040 West Georgia Street, Suite 1030, Vancouver, British Columbia, V6E 4H1, Attention: Chief Executive Officer (or other such address as the Company shall designate in writing to Indemnitee). Notice shall be deemed received three days after the date postmarked if sent by certified or registered mail, properly addressed. In addition, Indemnitee shall give the Company such information and cooperation as it may reasonably require and as shall be within Indemnitee's power.

11.**Attorneys' Fees.** In the event that any action is instituted by Indemnitee under this Agreement to enforce or interpret any of the terms hereof, Indemnitee shall be entitled to be paid all

court costs and expenses, including reasonable attorneys' fees, incurred by Indemnitee with respect to such action, unless as a part of such action, a court of competent jurisdiction determines that each of the material assertions made by Indemnitee as a basis for such action were not made in good faith or were frivolous. In the event of an action instituted by or in the name of the Company under this Agreement, or to enforce or interpret any other terms of this Agreement, Indemnitee shall be entitled to be paid all court costs and expenses, including attorneys' fees, incurred by Indemnitee in defense of such action (including with respect to Indemnitee's counterclaims and cross-claims made in such action), unless as a part of such action the court determines that each of Indemnitee's material defenses to such action were made in bad faith or were frivolous.

12.**Severability.** Should any provision of this Agreement, or any clause hereof, be held to be invalid, illegal or unenforceable, in whole or in part, the remaining provisions and clauses of this Agreement shall remain fully enforceable and binding on the parties.

13.**Modification and Waiver.** No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.

14.**Choice of Law.** The validity, interpretation, performance and enforcement of this Agreement shall be governed by the laws of the State of Delaware.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

ACHIEVE LIFE SCIENCES, INC.

By: ___
John Bencich, CEO

INDEMNITEE:

____

EXHIBIT A

UNDERTAKING AGREEMENT

This AGREEMENT is made on _____, ____, between ACHIEVE LIFE SCIENCES, INC., a Delaware corporation (the "Company") and _____, a member of the board of directors or an officer of the Company ("Indemnitee").

WHEREAS, Indemnitee may become involved in investigations, claims, actions, suits or proceedings which have arisen or may arise in the future as a result of Indemnitee's service to the Company; and

WHEREAS, Indemnitee desires that the Company pay any and all expenses (including, but not limited to, attorneys' fees and court costs) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in defending or investigating any such suits or claims and that such payment be made in advance of the final disposition of such investigations, claims, actions, suits or proceedings to the extent that Indemnitee has not been previously reimbursed by insurance; and

WHEREAS, the Company is willing to make such payments but, in accordance with Section 145 of the General Corporation Law of the State of Delaware, the Company may make such payments only if it receives an undertaking to repay from Indemnitee; and

WHEREAS, Indemnitee is willing to give such an undertaking;

NOW, THEREFORE, in consideration of the mutual promises contained herein, the parties agree as follows:

1. In regard to any payments made by the Company to Indemnitee pursuant to the terms of the Indemnification Agreement dated _____, ____, between the Company and Indemnitee, Indemnitee hereby undertakes and agrees to repay to the Company any and all amounts so paid promptly and in any event within thirty (30) days after the disposition, including any appeals, of any litigation or threatened litigation on account of which payments were made, but only to the extent that Indemnitee is ultimately found not entitled to be indemnified by the Company under the Bylaws of the Company and Section 145 of the General Corporation Law of the State of Delaware, or other applicable law.

2. This Agreement shall not affect in any manner rights which Indemnitee may have against the Company, any insurer or any other person to seek indemnification for or reimbursement of any expenses referred to herein or any judgment which may be rendered in any litigation or proceeding.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed on the date first above written.

By: ___
Achieve Life Sciences, Inc.

INDEMNITEE:

___

___
(Print Name)

EXHIBIT 10.21

DATED 14 May 2015

(1) EXTAB PHARMA, INC.

and

(2) SOPHARMA AD

SHARE PURCHASE AGREEMENT

1

CONTENTS

THIS AGREEMENT is made by way of a deed on 2015

BETWEEN:

(1) **EXTAB PHARMA, INC.** a company incorporated in the State of Delaware whose principal place of business is at Corporation Trust Centre, 1209 Orange Street, Wilmington, Delaware 19801, USA (the "**Buyer**"); and

(2) **SOPHARMA AD** a company incorporate in Bulgaria with company number 831902088 whose registered address is at 16 Iliensko Shosse Blvd., 1220 Sofia, Bulgaria (the "**Seller**").

IT IS AGREED as follows:-

1. **INTERPRETATION**

1.1 The definitions and rules of interpretation in this clause apply in this agreement,

ess" means the business carried on by the Company, namely its biopharmaceutical business in smoking cessation, including the marketing and seeking of regulatory approval in respect of the Product, or any part of it;

ess Day" means a day other than a Saturday, Sunday or public holiday in England or Bulgaria when banks in London and Bulgaria are open for business;

s Solictors" means Pinsent Masons LLP of 30 Crown Place, London EC2A 4ES, United Kingdom;

' means a claim for breach of any of the Warranties;

any" means Extab Corporation, a company incorporated in the State of Delaware with registered number 4619307 whose registered address is at Corporation Trust Centre, 1209 Orange Street, Wilmington, Delaware 19801, USA further details of which are set out in Schedule 1;

etion" means completion of the sale and purchase of the Sale Shares in accordance with this Agreement;

lential Information" all information not in the public domain and which is used in or which otherwise relates to the Seller's business, its customers or financial or other affairs, including, without limitation, information relating to:-

(a) the marketing of products or services including customer names and lists and other details of customers, financial information, sales targets, sales statistics, market share statistics, prices, market research reports and surveys, and advertising or other promotional materials; or

(b) future projects, business development or planning, commercial relationships and negotiations.

existing in whatever form;

ed Purchase Price" has the meaning set out in Clause 3.1.2;

or" means each person who is a director of the Company, as set out in Schedule 1;

nbrance" means any interest or equity of any person (including any right to acquire, option or right of first refusal, subscription or pre-emption), any voting agreement, voting trust or proxy, or any mortgage, charge, pledge, lien, assignment, hypothecation, security interest, title retention or any other security agreement or arrangement;

Territory" means all countries, territories and regions of the world, excluding the Sopharma Territory;

Pharma Limited" means Extab Pharma Limited incorporated and registered in England and Wales with company number 06751116 whose registered office is at 10 Station Road, Henley on Thames, Oxfordshire, RG9 1AY;

means the Food and Drug Administration in the United States;

mental Warranties" means the warranties given by the Seller under paragraphs 1.1, 1.2 and 2.2 of Schedule 3

" means in relation to a company, that company, any subsidiary or any holding company from time to time of that company, and any subsidiary from time to time of a holding company of that company. Each company in a Group is a **member of the Group**;

ctual Property" means patents, trade marks, service marks, logos, get-up, trade names, internet domain names, rights in designs, copyright (including rights in computer software), database rights, semi-conductor topography rights, utility models, rights in know-how and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all other rights or forms of protection having equivalent or similar effect anywhere in the world;

e Agreement" means the agreement between (1) the Seller and (2) the Company dated 26 May 2009 pursuant to which the Seller granted the Company an exclusive licence to use the Licensed IP in the Extab Territory to exploit the Product;

ed IP" means the Seller's Intellectual Property as set out in Schedule 4;

means a New Drug Application;

Agreement" means the option agreement to be entered into between (1) the Company and (2) the Seller on or around the date of this Agreement;

ct" means any pharmaceutical composition, device or combination product developed by or on behalf of the Company or by or on behalf of the Seller containing the active ingredient Cytisine and/or any intermediates, salts and/or esters of the same and in particular Tabex;

ase Price" means the purchase price for the Sale Shares as set out in Clause 3.1;

atory Approval" means, with respect to a territory, approval from the relevant Regulatory Authority for the prescribing and/or selling of the Product including, where required, pricing and reimbursement approvals;

atory Authority" means the FDA and/or the European Medicines Agency;

rma Territory" means Albania, Algeria, Armenia, Austria, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Finland, Georgia, Hungary, Kazakhstan, Kosovo, Kyrgyzstan, Latvia, Lithuania, Libya, Macedonia, Moldova, Mongolia, Norway, Poland, Romania, Russia, Serbia, Slovakia, Sweden, Tajikistan, Tunisia, Turkey, Turkmenistan, Ukraine, Uzbekistan, Vietnam, Iran and Afghanistan;

hares" means 1,125 shares of Common Stock, par value of US$0.001, of the Company, all of which have been issued and are fully paid and non-assessable;

e Documents" means any claim form, notice, order, judgment or other court document issued by the courts of England and Wales, or any other document relating to or in connection with proceedings in the courts of England and Wales;

/ Agreement" means the agreement between (1) the Company and (2) the Seller dated 1 February 2010 pursuant to which the Seller agreed to manufacture and supply the Product to the Company;

" means the medicinal product with active ingredient Cytisine for smoking cessation;

nties" means the warranties given pursuant to Clause 5 and set out in Schedule 3.

1.2 Reference to clauses and Schedules are to the clauses of, and Schedules to, this Agreement and references to paragraphs are to paragraphs of the relevant Schedule.

1.3 The Schedule form part of this Agreement and shall have effect as if set out in full in the body of this Agreement.

1.4 A reference to a **party** shall include that party's successors and permitted assigns.

1.5 A reference to a **company** shall include any company, corporation or other body corporate, wherever and however incorporated or established.

1.6 A reference to a **holding company** or a **subsidiary** means a holding company or a subsidiary (as the case may be) as defined in section 1159 of the Companies Act 2006.

1.7 A reference to **"writing"** or **"written"** includes fax but not email (unless otherwise expressly provided in this agreement).

1.8 Any words following the terms **including, include, in particular, for example** or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms. Where the context permits, **other** and **otherwise** are illustrative and shall not limit the sense of the words preceding them.

1.9 References to a document in **agreed form** is to that document in the form agreed by the parties and initialled by them or on their behalf for identification.

1.10 A reference to a statute, statutory provision or subordinate legislation is a reference to it as it is in force as at the date of this agreement. A reference to a statute or statutory provision shall include all subordinate legislation made as at the date of this agreement under that statute or statutory provision.

2. **SALE AND PURCHASE**

2.1 On the Completion Date, the Seller shall sell and the Buyer shall buy, with effect from Completion, the Sale Shares with full title guarantee, free from all Encumbrances and together with all rights attached or accruing to them in consideration of the payment by the Buyer of the Purchase Price.

2.2 The Seller covenants to the Buyer that it has the right to sell and transfer the whole of the legal, record and beneficial interest in and title to the Sale Shares to the Buyer.

2.3 The Seller covenants to the Buyer that the Sale Shares are free from all Encumbrances.

2.4 The Seller covenants to the Buyer that the Buyer will upon registration as owner of the Sale Shares be entitled to exercise all rights attached or accruing to such Sale Shares including, without limitation, the right to vote and the right to receive all dividends or other distributions or any return of capital declared, made or paid by the Company on or after such registration.

3. **PURCHASE PRICE**

3.1 The Purchase Price payable by the Buyer to the Seller for the Sale Shares shall be:

3.1.1 US$ 2,000,000 payable in case on completion in accordance with Clause 4.3.1; and

3.1.2 A further US$ 2,000,000 (the "**Deferred Purchase Price"**) payable in cash by electronic transfer of immediately available funds to the Seller's account detailed in Clause 4.3.1 within 10 Business days of the earlier of either:

(a) Regulatory Approval by the FDA; or

(b) Regulatory Approval by the European Medicines Agency.

For the avoidance of doubt, obtaining a Regulatory Approval from a regulatory authority other than the FDA or the European Medicines Agency shall not trigger an obligation on the part of the Buyer to pay the Deferred Purchase Price.

3.2 The Purchase Price shall be deemed to be reduced by the amount of any payment made to the Buyer in respect of any Claim.

3.3 The Buyer may at any time, but a written notice to the Seller, set off any liability of the Seller to the Buyer against any liability of the Buyer to the Seller, up to the maximum aggregate liabilities specified in clause 6.1, provided that the liabilities are present, executable and liquidated. If the liabilities to be set off are expressed in different currencies, the Buyer may convert either liability at a market rate of exchange for the purpose of set-off. Any exercise by the Buyer of its rights under this clause shall not limit or affect any other rights or remedies available to it under this agreement or otherwise.

4. **COMPLETION**

4.1 Completion shall take place on the Completion Date at the offices of the Buyer's Solicitors (or at any other place as may be agreed in writing by the parties).

4.2 At Completion, the Seller shall comply with its obligations in Schedule 2.

4.3 Subject to the Seller complying with Clause 4.2, the Buyer shall:

4.3.1 pay the initial portion of Purchase Price at Completion by electronic transfer of immediately available funds to the client account of the Seller, details of which are:

Bank: [Redacted]

IBAN: [Redacted]

BIC code: [Redacted]

Account name: [Redacted]

Payment in accordance with this clause shall be a good and valid discharge of the Buyer's obligation to pay the initial portion of the Purchase Price; and

4.3.2 deliver to the Seller a certified copy of the resolution adopted by the board of directors of the Buyer approving the execution and delivery of this Agreement and any other documents to be delivered by the Buyer at Completion;

4.3.3 cause the Company to pay to the Seller by electronic transfer to the bank account detailed at clause 4.3.1 above, the balance of the outstanding loans from the seller to the Company and Extab Pharma Limited, such loans in aggregate being the total sum of US$271,947.26.

4.4 This Agreement (other than obligations that have already been fully performed) shall remain in full force after Completion.

4.5 On Completion, the seller hereby appoints the Buyer as its lawful attorney for the purpose of signing any written resolutions (or receiving notices of and attending and voting at all meetings) of the members of the Company in respect of the Sale Shares during the period commencing from Completion and ending on the day on which the Buyer is entered in the register of members of the Company as the holder of the Sale Shares and this power of attorney (which is given by way of security to secure the performance of obligations owed by the seller to the Buyer under this Agreement) shall be irrevocable.

5. **WARRANTIES**

5.1 The Seller warrants that each Warranty is true, accurate and not misleading on the date of this Agreement and on the Completion Date.

5.2 Warranties qualified by the express so far as the seller is aware (or any similar expression) are deemed to be given to the best of the knowledge, information and belief of the Seller after it has made due and careful enquiries.

5.3 Each of the Warranties is separate and, unless otherwise specifically provided, is not limited by reference to any other Warranty or any other provision in this Agreement.

5.4 The Seller acknowledges that the Buyer is entering into this Agreement in reliance upon the Warranties which have also been given as representations with the intention of inducing the Buyer to enter into this Agreement.

5.5 No information of which the Buyer, its agents or advisers has knowledge (in each case whether actual, constructive or imputed), or which could have been discovered (whether by investigation made by the Buyer or on its behalf), shall prejudice or prevent any Claim, or reduce the amount recoverable under any Claim.

5.6 Without prejudice to the right of the Buyer to claim on any other basis or take advantage of any other remedies available to it, if any Warranty is breached or proves to be untrue or misleading, the Seller shall pay to the Buyer (each for itself and as trustee of the benefit of this Clause 5.6 for each Group Company) on demand:

5.6.1 the amount necessary to put each Group Company into the position they would have been in if the Warranty had not been breached or had not been untrue or misleading;

5.6.2 all costs and expenses (including, without limitation, damages, legal and other professional fees and costs, penalties, expenses and consequential losses whether arising directly or indirectly) incurred by the Buyer or any Group Company as a result of such breach, or of the Warranty being untrue or misleading including a reasonable amount in respect of management time);

5.6.3 any amount necessary to ensure that after any Tax of a payment made in accordance with Clause 5.6.1 or Clause 5.6.2, the Buyer is left with the same amount it would have had if the payment was not subject to Tax; and

5.6.4 for the avoidance of doubt all payments shall be within the limitations of the aggregate liability of the Seller specified in Clause 6.1

6. **LIMITATIONS ON CLAIMS**

6.1 The aggregate liability of the Seller for all Claims shall not exceed:

6.1.1 US$ 50,000 in respect of the warranties (other than the Fundamental warranties); and

6.1.2 US$ 2,000,000 in respect of the Fundamental Warranties.

6.2 The Seller shall not be liable for a Claim unless notice in writing of the Claim, summarising the nature of the Claim (in so far as it is known to the Buyer) and, as far as is reasonably practicable, the amount claimed, has been given by or on behalf f the Buyer to the Seller on or before the second anniversary of Completion.

6.3 Nothing in this Clause 6 applies to exclude or limit the liability of the Seller to the extent that a Claim arises or is delayed as a result of dishonesty, fraud, wilful misconduct or wilful concealment by the Seller, its subsidiaries and companies otherwise under its control.

7. **RESTRICTIONS ON THE SELLER**

7.1 As further consideration for the Buyer agreeing to purchase the Sale Shares and with the intent of securing to the Buyer the full benefit and value of the goodwill and connections of the Company the Seller undertakes to the Buyer that it, and its wholly owned subsidiaries, will not:-

7.1.1 for a period of 3 years from Completion, an any capacity whatsoever, directly or indirectly carry on or assist in carrying on or be engaged, concerned or interested in any activity or undertaking which is the same as, or substantially similar to, the Business within the Extab Territory; and

7.1.2 for a period of 3 years from Completion for the purpose of any business supplying products or services similar to or capable of being used in substitution for any product or service supplied by the Company within the 12 months preceding Completion, canvass, solicit or endeavour to entice away from the Company any person who during the period of two years prior to Completion has been a customer of the Company or has purchased or agreed or offered to purchase goods from the Company or has employed its services; and

7.1.3 for a period of 3 years from Completion do any act or thing likely to have the effect of causing any supplier of or other person in the habit of dealing with the Company to be unable or unwilling to deal with the Company either at all or in part or on the terms on which it had previously dealt with the Company or likely to have the effect of causing any person having a contract or arrangement with the Company to breach, terminate or modify that contract or arrangement or to exercise any right under it.

7.2 Each of the undertakings contained in Clause 7.1 is separate and severable and shall be construed on that basis. In the event that any of such undertakings is found to be void but would be valid if some part of it were deleted or if the period or extent of it were reduced such undertaking shall apply with such modification as may be necessary to make it valid and effective.

8. **CONFIDENTIALITY AND ANNOUNCEMENTS**

8.1 Except to the extent required by law or any legal or regulatory authority of competent jurisdiction:

8.1.1 the Seller shall not (and shall procure that no member of the Seller's Group shall) at any time disclose to any person (other than its professional advisers) the terms of this Agreement or any trade secret or other confidential information relating to the Company or the Buyer, or make any use of such information other than to the extent necessary for the purpose of exercising or performing its rights and obligations under this Agreement;

8.1.2 subject to Clause 8.2 and Clause 8.3 neither party shall make, or permit any person to make, any public announcement, communication circular concerning this agreement without the prior written consent of the other party.

8.2 The Buyer may, at any time after Completion, announce its acquisition of the Sale Shares to any employees, clients, prospective purchasers, investors, customers or suppliers of the Company or any other member of the Buyer's Group.

8.3 Clause 8.1 does not apply to an announcement communication or circular required by law or the rules of any stock exchange or by any other regulatory body.

9. **FURTHER ASSURANCE**

The Seller shall (at its own expense) promptly execute and deliver such documents perform such acts and do such things as the Buyer may reasonably require from time to time for the purpose of giving full effect to this Agreement.

10. **ASSIGNMENT**

Neither party shall assign, transfer, mortgage, charge, declare a trust of, or deal in any other manner with any of its rights and obligations under this Agreement without the prior written consent of the other party.

11. **ENTIRE AGREEMENT**

This Agreement together with the agreed form documents constitutes the entire agreement between the parties and supersedes and extinguishes all previous discussions, correspondence, negotiations, drafts agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

12. **VARIATION AND WAIVER**

12.1 No variation of this Agreement shall be effective unless it is in writing and signed by the parties (or their authorized representatives).

12.2 No failure or delay by a party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy. A waiver of any right or remedy under this Agreement or by law is only effective it is in writing.

12.3 Except as expressly provided in this Agreement, the rights and remedies provided under this agreement are in addition to, and not exclusive of any rights or remedies provided by law.

13. **NOTICES**

13.1 A notice given to a party under or in connection with this agreement shall be in writing in the English language and shall be delivered by hand or sent by pre-paid first-class post recorded delivery or special delivery in each case to that party's registered office, or sent by airmail or email.

13.2 Delivery of a notice is deemed to have taken place (provided that all other requirements in this Clause 13 have been satisfied) if delivered by hand, at the time the notice is left at the address, or if sent by fax, at the time of transmission, or if sent by post on the second Business Day after posting, unless such deemed receipt would occur outside business hours (meaning 9:00 am to 5:30 pm Monday to Friday on a day that is not a public holiday in the place of deemed receipt), in which case deemed receipt will occur when business next starts in the place of receipt (and all reference to time are to local time in the place of receipt).

13.3 This Clause 13 does not apply to the service of any proceedings or other documents in any legal action.

14. **SERVICES OF PROCESS**

Each party to this Agreement agree that any Service Document in relation to this Agreement must be sent by pre-paid first-class post to the addresses set out at the commencement of this Agreement or to such other address as either party may notify to the other from time to time.

15. **SEVERANCE**

If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable if such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of this Agreement.

16. **DISPUTE RESOLUTION**

16.1 Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the LCIA Rules, which rules are deemed to be incorporated by reference into this clause.

16.2 The number of arbitrators shall be one.

16.3 The seat or legal place or arbitration shall be London, England.

16.4 The language to be used in the arbitral proceedings shall be English.

16.5 The governing law of the Agreement shall be the substantive law of England.

16.6 The Parties undertake to keep confidential all awards in any arbitration, together with all materials in the proceedings created for the purpose of the arbitration and all other documents produced by another party in the proceedings not otherwise in the public domain, save and to the extent that disclosure may be required of a party by legal duty or a regulatory authority (including but not limited to any stock exchange), to protect or pursue a legal right or to enforce or challenge an award in bona fide legal proceedings before a state court or other judicial authority.

16.7 By agreement to arbitration in accordance with this clause, the Parties do not intend to deprive any competent court of its jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings or the enforcement of any award.

SIGNED by or on behalf of the parties as a **DEED** on the date which first appears in this Agreement.

SCHEDULE 1
PARTICULARS OF THE COMPANY

Name Extab Corporation

Registration number: 4619307

Registered address: Corporation Trust Centre, 1209 Orange Street, Wilmington, Delaware 19801 USA

Issued share capital: Amount: US $1.50

Divided into: 1,500 shares of Common Stock of US$ 0.001 each

Directors: Richard Stewart

Ognian Donev

Secretary: Richard Stewart

Auditors: Kench and Company

Registered charges: None

SCHEDULE 2
COMPLETION

1. At Completion, the Seller shall deliver to the Buyer:

1.1 the certificate or certificates representing the Sale Shares duly endorsed in blank, or a duly executed affidavit of lost certificate, in agreed form;

1.2 an executed stock power with respect to the Sale Shares, in agreed form;

1.3 the stock ledger and minute books (duly written up to the time of Completion), the common seal (if any), certificate of incorporation and bylaws of the Company;

1.4 bank statements for reach of the Company's bank accounts showing the balances at the close of business on the Business Day before Completion;

1.5 a certified copy of the resolution, in agreed form, of the board of directors of the Seller approving the execution and delivery of this Agreement and any other documents to be delivered by the Seller at Completion;

1.6 the following amended and duly re-executed agreements in the agreed form:

1.6.1 Supply Agreement;

1.6.2 Licence Agreement;

1.7 the duly executed Option Agreement in the agreed form;

1.8 any relevant clearance required and obtained from industry regulators; and

1.9 all necessary consents required from the Seller's shareholders by reason of being a company listed on the Bulgarian Stock Exchange.

2. The Seller shall cause a board meeting of the Company to be held at Completion at which the matters set out in the agreed form completion board minutes shall take place.

SCHEDULE 3
WARRANTIES

1. **POWER TO SELL THE SALE SHARES**

1.1 The Seller has the requisite power and authority to enter into and perform this Agreement and the documents referred to in it (to which it is a party), and they constitute valid, legal and binding obligations on the Seller in accordance with their respective terms.

1.2 The execution and performance by the Seller of this Agreement and the documents referred to in it have been duly authorized by all necessary company action and will not breach or constitute a default under the Seller's articles of association, or any agreement, instrument, order, judgement or other restriction which binds the Seller.

2. **SHARES IN THE COMPANY**

2.1 The Sale Shares constitute 75 per cent of the outstanding shares of capital stock of the Company and have been duly issued by the Company, are fully paid and non-assessable.

2.2 The Seller is the sole legal, record and beneficial owner of the Sale Shares and is entitled to transfer the legal and beneficial title to the Sale Shares to the Buyer free from all Encumbrances, without the consent of any other person.

2.3 No person has any right to require at any time the transfer, creation, issue or allotment of any share, loan capital or other securities of the Company (or any rights or interest in them), and no person has agreed to confer or has claimed any such right.

2.4 No Encumbrance has been granted to any person or otherwise exists affecting the Sale Shares or any unissued shares, debentures or other unissued securities of the Company, and no commitment to create any such Encumbrance has been given, nor has any person claimed any such rights.

3. **INFORMATION**

3.1 The particulars set out in Schedule 1 are true, accurate and complete.

3.2 All information given by or on behalf of the Seller to the Buyer (or its agents or advisers) in the course of the negotiations leading up to this Agreement, was when given, and is now, true, accurate and complete.

4. **INTELLECTUAL PROPERTY**

4.1 Schedule 4 contains a complete and accurate list of (a) all registered Intellectual Property and (b) all unregistered Intellectual Property material for the carrying on the business of the Seller or which otherwise comprises a significant asset of the Seller, in each case owned by the Seller (the "**Owned Intellectual Property"**).

4.2 The Seller described as the owner or applicant of the Owned Intellectual Property in Schedule 4 is the sole legal and beneficial owner of such rights free from all Encumbrances.

4.3 None of the registrations or applications included in the Owned Intellectual Property is subject to, or (so far as the Seller is aware) likely to be subject to, amendment, challenge,

removal or surrender. So far as the seller is aware, there is nothing which may prevent any of the applications comprised in the Owned Intellectual Property being granted.

4.4 In respect of all Owned Intellectual Property registered or applied for by or on behalf of the Seller, all application, filing, registration, renewal and other fees have been paid as and when due and all other steps required for the prosecution, maintenance and protection of the same have been taken on a timely basis.

4.5 No compulsory licences or licences of right have been or are likely to be granted in respect of any of the Owned Intellectual Property.

4.6 The Seller has disclosed to the Company and the Buyer complete and accurate details of all licences of Intellectual Property granted by any Group company and all licences of Intellectual Property granted to any Group company (in each case including, without limitation, research and development agreements, letters of consent, undertakings, and co-operation agreements entered into by any Group company ("**IP Licences"**).

4.7 Each of the IP Licences is binding and in force. None of the parties to the IP Licences are in breach thereof and there is no fact or matter which would or may give rise to a breach of any of the IP Licences.

4.8 No notice to terminate any of the IP Licences has been given or threatened and there are no other grounds on which any of the IP Licences may be terminated. No disputes have arisen or are foreseeable in connection with any IP Licence.

4.9 The Seller owns, or has licensed to it, all Intellectual Property which is used or required to be used, in or in connection with its business as presently carried on.

4.10 No person has asserted any moral or similar right in respect of any Owned Intellectual Property or any Intellectual Property which is the subject of any IP Licence, and the seller has not breached any moral right of any third party.

4.11 None of the processes and methods employed, the business conducted, the services provided or the products manufactured, used or dealt with by the Seller company infringes, or has at any time in the 5 years prior to the date of this Agreement, infringed any Intellectual Property of any third party.

4.12 No claim has been made by a third party which alleges that any of the operations of the Seller infringes, or is likely to infringe, the Intellectual Property of any third party or which disputes the right the Seller to use Intellectual Property which is used by the Seller. The Seller is not aware of any circumstances likely to give rise to any such claim.

4.13 So far as the Seller is aware there exists no actual or threatened infringement of any of the Owned Intellectual Property or any circumstances likely to constitute such an infringement. The Seller has not acquiesced in the unauthorized use by any third party of any Owned Intellectual Property.

4.14 There is (and has during the 3 years preceding the date of this Agreement been) no civil, criminal, arbitration, administrative or other proceedings or dispute in any jurisdiction concerning any of the Owned Intellectual Property. No such proceedings or dispute are pending or threatened and no matter exists which might give rise to such proceedings or dispute.

4.15 The Seller has not disclosed or agreed to disclose any Confidential Information or know-how to any person other than (i) to its employees who are bound by obligations of confidence or

(ii) properly in the ordinary and usual course of business of the Seller and on condition that the disclosure is to be treated as being of a confidential nature, and in each case where such Confidential Information or know-how is material to the business of the Seller, the Seller has received a written undertaking of confidentiality from the recipient.

4.16 The Seller is a party to a confidentiality or other agreement which restricts the free use or disclosure of information used in its business.

4.17 There are no injunctions, undertakings, order, agreements or arrangements which restrict the disclosure, use or assignment by the Seller of any of the Owned Intellectual Property.

4.18 None of the Owned Intellectual Property or the IP Licences will be lost or rendered liable to termination by virtue of the acquisition of the Seller's business or the performance of this Agreement.

4.19 None of the employees or ex-employees of the Seller has created any work the Intellectual Property in which is used by the Seller, except in the course of his employment by the Seller, and all Intellectual Property in such work is vested in the Seller.

4.20 Materially complete and accurate records, files and documents have been maintained for all Intellectual Property Rights and such records, files and documents are in the possession or under the control of the Seller.

SCHEDULE 4
LICENSED IP

1. **REGISTERED INTELLECTUAL PROPERTY**

PATENT	REG. NO.	TERRITORY
[Redacted]		

TRADEMARK	REG. NO.	TERRITORY
[Redacted]		

2. **UNREGISTERED INTELLECTUAL PROPERTY**

2.1 Technology for obtaining Citizine from Cytisum laburnum;

2.2 Solid dosage tablet pharmaceutical composition containing Citizine. A method and technology for preparation of it.

SIGNED by)
A duly authorized officer)
For and on behalf of)
EXTAB PHARMA, INC.)
in the presence of:)

Signature of Witness:

Name of Witness:

Address:

Occupation:

SIGNED by)
A duly authorized officer)
For and on behalf of)
SOPHARMA AD)
in the presence of:)

Signature of Witness:

Name of Witness:

Address:

Occupation:

EXHIBIT 10.32

RENEWAL SERVICE AGREEMENT

AGREEMENT DATE: NOVEMBER 9, 2023

BUSINESS CENTER ADDRESS :	CLIENT ADDRESS (NOT A BUSINESS CENTER ADDRESS):
Regus	**Company Name** Achieve Life Sciences
	Contact Name Kevin Nouwens
WA, Bothell – Canyon Park West	**Address*** 520 Pike Street
22722 29th Drive SE	Suite 2250
Suite 100	
Washington	City: Seattle
98021	**State/County/Province** Washington
	Municipality/Governorate*
United States of America	**Post Code *** 98021
	Country * United States of America
	Phone number * United States of America 206-920-7606
	Email *

RENEWAL PAYMENT DETAILS (EXCLUDING TAX AND OPTIONS SERVICES)

Office Number	Number of People	Total Monthly Office Price
173	1	$ 1,284.00
TOTALS	1	**$ 1,284.00**

SERVICE PROVISION: Start Date	March 1, 2024	End Date*	February 28, 2025

COMMENTS

* All agreements end on the last calendar day of the month.
•Invoices/Fess are charged on a monthly basis which is calculated based on a 30-day month.
•A refundable service retainer equivalent to 2 x monthly office fee will be payable

TERMS AND CONDITIONS

We are Regus Management Group,LLC, please click the link below for terms and conditions.

AGREEMENT TO ARBITRATE;CLASS ACTION WAIVER:Any dispute or daim relating In any way to this agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with Its Commercial Arbitration Rules (available at www.adr.org), except that You or We may assert dams in small claims court and You and We may pursue court actions to remove You, or prevent Your removal, from the Center if You do not leave when this agreement terminates. The arbitrator shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement. The arbitrator shall not conduct arbitration as a class or representative action. You and We acknowledge that this agreement is a transaction in interstate commerce governed by the Federal Arbitration Act. You and We agree to waive any right to pursue any dispute relating to this agreement in any class, private attorney general, or other representative action.

CONFIRMATION NO : R-2749796

CONFIRMATION NO : R-2749796

These General Terms and Conditions apply to Office/Co-Working, Virtual Office, and Membership agreements for services We supply to You.

1. General Agreement

1.1 Nature of an agreement: At all times, each Center remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE, OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOR WITH RESPECT TO THE ACCOMMODATION.

1.2 House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.

1.3 Company and Contact Information: It is Your responsibility to keep the information and key contact information We use to communicate with You up to date through the App or Online Account (or other customer portal as advised to you from time to time). This includes but is not limited to email addresses, phone numbers, and company address. Your contact address details must be a legitimate business address or residential address of the primary contact; it must not be an IWG Center address (or other business center address).

1.4 Availability at the start of an agreement: If for any unfortunate reason We cannot provide the Virtual Office services or Office/Co-Working accommodation in the Center stated in an agreement by the start date, We will have no liability to You for any loss or damage, but You may either move to one of Our other Centers (subject to availability), delay the start of the agreement, or cancel it.

1.5 AUTOMATIC RENEWAL: SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW, THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS:

Term	Notice Period
Month-to-Month	no less than 1 month's notice from the 1st day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

..6 We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, according to the same notice periods specified above.

..7 If the Center is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Center stated in an agreement, We will offer You accommodation in one of Our other centers. In the unlikely event We are unable to find

a nearby alternative accommodation, Your agreement will end, and You will only have to pay monthly fees up to that date and for any additional services You have used.

..8 Ending an agreement immediately: We may terminate an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Center with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the “Compliance With Law” clause below. If We terminate an agreement for any of the reasons referred to in this clause You must, within 30 days of the date of Our notice of termination, pay Us as a lump sum payment all sums that would otherwise have fallen due and payable by you during the remainder of the period for which Your agreement would have lasted if We had not terminated it. You agree that this payment reflects a reasonable estimate of the actual damages that We will sustain in the event of an early termination.

..9 When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. If You leave any property in the Center, We may dispose of it at Your cost in any way We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.

..10. Transferability: Subject to availability (which shall be determined in Our sole discretion) You may transfer Your agreement to alternative accommodation in the IWG network of Centers provided that Your financial commitment remains the same (or increases) and such transfer is not used to extend or renew an existing agreement. Such a transfer may require entry into a new agreement.

. Use of the Centers:

!.1. Business Operations: You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Center as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Center provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.

!.2 Accommodation

1. Alterations or Damage: You are liable for any damage caused by You or those in the Center with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.

2. IT Installations: We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT, or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us to oversee any installations (for example, IT or

electrical systems) and to verify that such installations do not interfere with the use of the accommodation by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.

3. Use of the Accommodation: An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Where the accommodation is a Coworking desk, this can only be used by one individual. It cannot be shared among multiple individuals. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size, and We will notify You with respect to such different accommodation in advance.

4. Access to the Accommodation: To maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including and without limitation, in an emergency, for cleaning and inspection or in order to resell the space if You have given notice to terminate. We will always endeavor to respect any of Your reasonable security procedures to protect the confidentiality of Your business.

5. Hybrid Working: You may use Your designated office for hybrid working (excluding Coworking desks). Hybrid working is defined as having more individuals registered with access to Your office than the specified maximum allowable occupants for that office at any one time. The management of individuals accessing your office is Your responsibility and should be managed through Your online account. At no time may the number of individuals working in Your accommodation exceed the maximum number of occupants allowed. A hybrid supplemental monthly fee will be payable by You for each individual registered above the maximum occupants allowed. This fee can be found in the House Rules.

Membership:

1. If You have subscribed to a Membership Agreement, You will have access to all participating centers worldwide during standard business working hours and subject to availability.

2 Membership Usage: Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the center at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any additional guests will be required to purchase a day pass.

3. As a Member, You may not use any Center as Your business address without an accompanying office or virtual office agreement in place. Any use of the Center address in such a way will result in an automatic enrollment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.

4. Compliance with Law: You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Center by Us or by others (including but not limited to political campaigning or immoral

activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Center, or You are or will become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.

2.5. Ethical Trading: Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery, and anti- corruption laws.

2.6. Data Protection:

1. Each party shall comply with all applicable data protection legislation. The basis on which we will process Your personal data is set out in our privacy policies (available on our website at www.iwgplc.com/clientprivacypolicy.)

2. You acknowledge and accept that we may collect and process personal data concerning You and/or your personnel in the course of our agreement for services with you. Such personal data will be processed in accordance with our privacy policy. Where you provide this data to us, you will ensure that you have the necessary consents and notices in place to allow for this.

2.7. Employees: We will both have invested a great deal in training Our staff. Therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in any Center (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand the other the equivalent of 6 months' salary of any employee concerned.

2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after an agreement ends.

2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.

2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Center is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.

3. Our liability to You and Insurance

3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike, or other event outside of Our reasonable control otherwise, unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give

Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement, then, subject to the exclusions and limits set out immediately below, We will pay any actual and reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.

3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Center, for any mail You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.

3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.

3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:

3.5.1 without limit for personal injury or death;

2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and

3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).

es

4.1. Service Retainer/Deposit: Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We will require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held, and/or You frequently fail to pay invoices when due.

4.2. Taxes and duty charges: You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such

payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, duties or other documentary taxes and fees.

4.3. Payment: We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card (wherever local banking systems permit). If You do not set up an automatic form of payment, You will be charged a refundable payment retainer equal to one time your monthly product fee. Invoices are due and payable on the due date stated in them.

4.4. Late payment: If You do not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If any part of an invoice is legitimately disputed, You shall give immediate written notice to Us, follow the requirements of the Disputes clause in the House Rules, and pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Center where applicable) while there are any outstanding fees and/or interest or You are in breach of an agreement.

4.5. Insufficient Funds: Due to the additional administration We incur, You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

4.6. Activation: An activation fee is payable in respect of each agreement You have with Us (including any new agreements entered into under clause 1.10 above). This fee covers the administrative cost of the client onboarding process and account setup. This fee is set out in each Local Services Agreement and is charged on a per occupant basis for Serviced Office and Coworking (dedicated desk), on a per location basis for Virtual Office, and on a per person basis for Membership. Further information is set out in the House Rules.

4.7. Indexation: If an agreement, including month to month agreements, continues for more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the current House Rules. If a country experiences high levels of inflation, indexation could be applied more frequently and is detailed in the current House Rules.

4.8. Office Restoration: Upon Your departure or if You choose to relocate to a different room within a Center, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear.

4.9. Standard services: Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than one month, the fee will be applied on a daily basis.

4.10. Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.

4.11. Additional Fees: If Your use of the accommodation or treatment of the accommodation requires Us to incur additional costs for the provision of nonstandard service(s), including but not limited to deep cleaning, unusual trash removal, pest remediation, or additional security, We reserve the right to charge You for the cost of these services plus an additional 20% administration fee.

4.12. Discounts, Promotions and Offers: If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.

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. 333-168820, 333-190480, 333-197937, 333-206569, 333- 221473, 333-228253, 333-231520, 333-236059, 333-238505, 333-254156, 333-263421 and 333-270625), Form S-1 (File Nos. 333-228596, 333-232817, 333-234530, 333-238970, 333-250074 and 333-251088) and Form S-3 (File Nos. 333-261811, 333-269059 and 333-272641) of Achieve Life Sciences, Inc. of our report dated March 28, 2024 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP

Chartered Professional Accountants

Vancouver, Canada
March 28, 2024

Exhibit 31.1

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 28, 2024

/s/ JOHN BENCICH
John Bencich
Chief Executive Officer (Principal Executive and Financial 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, John Bencich, Chief Executive Officer and Principal Executive and Financial 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, 2023 (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.

Date: March 28, 2024

/s/ JOHN BENCICH
John Bencich
Chief Executive Officer (Principal Executive and Financial Officer)

EXHIBIT 97.0

ACHIEVE LIFE SCIENCES, INC.

COMPENSATION RECOVERY POLICY

(Adopted August 15, 2023)

The Board has determined that it is in the best interests of the Company and its stockholders to adopt this Policy enabling the Company to recover from specified current and former Company executives certain incentive-based compensation in the event of an accounting restatement resulting from material noncompliance with any financial reporting requirements under the federal securities laws. Capitalized terms are defined in Section 14.

This Policy is designed to comply with Rule 10D-1 of the Exchange Act and shall become effective on the Effective Date and shall apply to Incentive-Based Compensation Received by Covered Persons on or after the Listing Rule Effective Date.

1.Administration

This Policy shall be administered by the Administrator. The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Administrator may retain, at the Company's expense, outside legal counsel and such compensation, tax or other consultants as it may determine are advisable for purpose of administering this Policy.

2.Covered Persons and Applicable Compensation

This Policy applies to any Incentive-Based Compensation Received by a person (a) after beginning service as a Covered Person; (b) who served as a Covered Person at any time during the performance period for that Incentive-Based Compensation; and (c) was a Covered Person during the Clawback Period.

However, recovery is not required with respect to:

i. Incentive-Based Compensation Received prior to an individual becoming a Covered Person, even if the individual served as a Covered Person during the Clawback Period.

ii. Incentive-Based Compensation Received prior to the Listing Rule Effective Date.

iii. Incentive-Based Compensation Received prior to the Clawback Period.

iv. Incentive-Based Compensation Received while the Company did not have a class of listed securities on a national securities exchange or a national securities association, including the Exchange.

The Administrator will not consider the Covered Person's responsibility or fault or lack thereof in enforcing this Policy with respect to recoupment under the Final Rules.

3.Triggering Event

Subject to and in accordance with the provisions of this Policy, if there is a Triggering Event, the Administrator shall require a Covered Person to reimburse or forfeit to the Company the Recoupment Amount applicable to such Covered Person. A Company's obligation to recover the Recoupment Amount is not dependent on if or when the restated financial statements are filed.

4.Calculation of Recoupment Amount

The Recoupment Amount will be calculated in accordance with the Final Rules, as provided in the Calculation Guidelines attached hereto as Exhibit B.

5.Method of Recoupment

Subject to compliance with the Final Rules and applicable law, the Administrator will determine, in its sole discretion, the method for recouping the Recoupment Amount hereunder which may include, without limitation:

i. Requiring reimbursement or forfeiture of the pre-tax amount cash Incentive-Based Compensation previously paid;

ii. Offsetting the Recoupment Amount from any compensation otherwise owed by the Company to the Covered Person, including without limitation, any prior cash incentive payments, executive retirement benefits, wages, equity grants or other amounts payable by the Company to Covered Person in the future;

iii. Seeking recovery of any gain realized on the vesting, exercise, settlement, cash sale, transfer, or other disposition of any equity-based awards; and/or

iv. Taking any other remedial and recovery action permitted by law, as determined by the Administrator.

6.Arbitration

To the fullest extent permitted by law, any disputes under this Policy shall be submitted to mandatory binding arbitration (the "***Arbitrable Claims***"), governed by the Federal Arbitration Act (the "***FAA***"). Further, to the fullest extent permitted by law, no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in Covered Person's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding.

SUBJECT TO THE ABOVE PROVISO, ANY RIGHTS THAT COVERED PERSON MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS ARE WAIVED. ANY RIGHTS THAT COVERED PERSON MAY HAVE TO PURSUE OR PARTICIPATE IN A CLASS OR COLLECTIVE ACTION PERTAINING TO ANY CLAIMS BETWEEN COVERED PERSON AND THE COMPANY ARE WAIVED.

Covered Person is not restricted from filing administrative claims that may be brought before any government agency where, as a matter of law, Covered Person's ability to file such claims may not be restricted. However, to the fullest extent permitted by law, arbitration shall be the exclusive

remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Seattle, Washington through JAMS before a single neutral arbitrator, in accordance with the JAMS Comprehensive Arbitration Rules and Procedures then in effect, provided however, that the FAA, including its procedural provisions for compelling arbitration, shall govern and apply to this Arbitration provision. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. If, for any reason, any term of this Arbitration provision is held to be invalid or unenforceable, all other valid terms and conditions herein shall be severable in nature and remain fully enforceable.

7.Recovery Process; Impracticability

Actions by the Administrator to recover the Recoupment Amount will be reasonably prompt.

The Administrator must cause the Company to recover the Recoupment Amount unless the Administrator shall have previously determined that recovery is impracticable and one of the following conditions is met:

i.The direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered; before concluding that it would be impracticable to recover any amount of erroneously awarded compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such erroneously awarded compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;

ii.Whether recovery would violate home country law where that law was adopted prior to November 28, 2022; before concluding that it would be impracticable to recover any amount of erroneously awarded compensation based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

iii.Whether recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

8.Non-Exclusivity

The Administrator intends that this Policy will be applied to the fullest extent of the law. Without limitation to any broader or alternate clawback authorized in any written document with a Covered Person, (i) the Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy, and (ii) this Policy will nonetheless apply to Incentive-Based Compensation as required by the Final Rules, whether or not specifically referenced in those arrangements. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies or regulations available or applicable to the Company (including SOX 304). If recovery is required under both SOX 304 and this Policy, any amounts recovered pursuant to SOX 304 may be credited toward the amount recovered under this Policy, or vice versa.

9.No Advancement and/or Indemnification

The Company shall not advance and/or indemnify any Covered Persons against the loss of erroneously awarded Incentive-Based Compensation or any adverse tax consequences associated with any incorrectly awarded Incentive-Based Compensation or any recoupment hereunder. For the avoidance of doubt, this prohibition on advancement and/or indemnification will also prohibit the Company from reimbursing or paying any premium or payment of any third-party insurance policy to fund potential recovery obligations obtained by the Covered Person directly. No Covered Person will seek or retain any such prohibited advancement, indemnification or reimbursement.

10.Covered Person Acknowledgement and Agreement

All Covered Persons subject to this Policy must acknowledge their understanding of, and agreement to comply with, the Policy by executing the certification attached hereto as Exhibit A.

11.Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators or other legal representatives and shall inure to the benefit of any successor to the Company.

12.Interpretation of Policy

To the extent there is any ambiguity between this Policy and the Final Rules, this Policy shall be interpreted so that it complies with the Final Rules. If any provision of this Policy, or the application of such provision to any Covered Person or circumstance, shall be held invalid, the remainder of this Policy, or the application of such provision to Covered Persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

In the event any provision of this Policy is inconsistent with any requirement of any Final Rules, the Administrator, in its sole discretion, shall amend and administer this Policy and bring it into compliance with such rules.

Any determination under this Policy by the Administrator shall be conclusive and binding on the applicable Covered Person. Determinations of the Administrator need not be uniform with respect to Covered Persons or from one payment or grant to another.

13.Amendments; Termination

The Administrator may make any amendments to this Policy as required under applicable law, rules and regulations, or as otherwise determined by the Administrator in its sole discretion.

The Administrator may terminate this Policy at any time.

14.Definitions

"***Administrator***" means the Compensation Committee of the Board, or in the absence of a committee of independent directors responsible for executive compensation decisions, a majority of the independent directors serving on the Board.

"***Board***" means the Board of Directors of the Company.

"***Clawback Measurement Date***" is the earlier to occur of:

i. The date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described in this Policy; or

ii. The date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described in this Policy.

"***Clawback Period***" means the three (3) completed fiscal years immediately prior to the Clawback Measurement Date and any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year (that results from a change in the Company's fiscal year) within or immediately following such three (3)-year period; provided that any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of 9 to 12 months will be deemed a completed fiscal year.

"***Company***" means Achieve Life Sciences, Inc., a Delaware corporation, or any successor corporation.

"***Covered Person***" means any Executive Officer (as defined in the Final Rules), including, but not limited to, those persons who are or have been determined to be "officers" of the Company within the meaning of Section 16 of Rule 16a-1(f) of the rules promulgated under the Exchange Act, and "executive officers" of the Company within the meaning of Item 401(b) of Regulation S-K, Rule 3b-7 promulgated under the Exchange Act, and Rule 405 promulgated under the Securities Act of 1933, as amended; provided that the Administrator may identify additional employees who shall be treated as Covered Persons for the purposes of this Policy with prospective effect, in accordance with the Final Rules.

"***Effective Date***" means August 15, 2023, the date the Policy was adopted by the Board.

"***Exchange***" means The Nasdaq Capital Market or any other national securities exchange or national securities association in the United States on which the Company has listed its securities for trading.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Final Rules***" means the final rules promulgated by the SEC under Section 954 of the Dodd-Frank Act, Rule 10D-1 and Exchange listing standards, as may be amended from time to time.

"***Financial Reporting Measure***" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and TSR are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC.

"***Incentive-Based Compensation***" means compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure. [Examples of "Incentive-Based Compensation" include, but are not limited to: non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal;

bonuses paid from a “bonus pool,” the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and SARs that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure goal. “Incentive-Based Compensation” excludes, for example, time-based awards such as stock options or restricted stock units that are granted or vest *solely* upon completion of a service period; awards based on non-financial strategic or operating metrics such as the consummation of a merger or achievement of non-financial business goals; service-based retention bonuses; discretionary compensation; and salary.

“***Listing Rule Effective Date***” means the effective date of the listing standards of the Exchange on which the Company’s securities are listed.

“***Policy***” means this Compensation Recovery Policy.

Incentive-Based Compensation is deemed “***Received***” in the Company’s fiscal period during which the relevant Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, irrespective of whether the payment or grant occurs on a later date or if there are additional vesting or payment requirements, such as time-based vesting or certification or approval by the Compensation Committee or Board, that have not yet been satisfied.

“***Recoupment Amount***” means the amount of Incentive-Based Compensation received by the Covered Person based on the financial statements prior to the restatement that exceeds the amount such Covered Person would have received had the Incentive-Based Compensation been determined based on the financial restatement, computed without regard to any taxes paid (*i.e.*, gross of taxes withheld).

“***SARs***” means stock appreciation rights.

“***SEC***” means the U.S. Securities and Exchange Commission.

“***SOX 304***” means Section 304 of the Sarbanes-Oxley Act of 2002.

“***Triggering Event***” means any event in which the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“***TSR***” means total stockholder return.

EXHIBIT A

Certification

I certify that:

1.I have read and understand the Company's Compensation Recovery Policy (the "***Policy***"). I understand that the Company is available to answer any questions I have regarding the Policy.

2.I understand that the Policy applies to all of my existing and future compensation-related agreements with the Company, whether or not explicitly stated therein.

3.I agree that notwithstanding the Company's certificate of incorporation, bylaws, and any agreement I have with the Company, including any indemnity agreement I have with the Company, I will not be entitled to, and will not seek advancement and/or indemnification from the Company for, any amounts recovered or recoverable by the Company in accordance with the Policy.

4.I understand and agree that in the event of a conflict between the Policy and the foregoing agreements and understandings on the one hand, and any prior, existing or future agreement, arrangement or understanding, whether oral or written, with respect to the subject matter of the Policy and this Certification, on the other hand, the terms of the Policy and this Certification shall control, and the terms of this Certification shall supersede any provision of such an agreement, arrangement or understanding to the extent of such conflict with respect to the subject matter of the Policy and this Certification.

Signature:

Name:

Title:

Date:

EXHIBIT B

Calculation Guidelines

For purposes of calculating the Recoupment Amount:

i. For cash awards, the erroneously awarded compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was received and the amount that should have been received applying the restated Financial Reporting Measure.

ii. For cash awards paid from bonus pools, the erroneously awarded compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

iii. For equity awards, if the shares, options, restricted stock units, or SARs are still held at the time of recovery, the erroneously awarded compensation is the number of such securities received in excess of the number that should have been received applying the restated Financial Reporting Measure (or the value of that excess number). If the options or SARs have been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the excess options or SARs (or the value thereof). If the underlying shares have been sold, the Company may recoup proceeds received from the sale of shares.

iv. For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

a. The amount must be based on a reasonable estimate of the effect of the accounting restatement on the stock price or TSR upon which the Incentive-Based Compensation was Received; and

b. The Company must maintain documentation of the determination of that reasonable estimate and the Company must provide such documentation to the Exchange in all cases.