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, 2025

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, 2025, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was $103,958,994 computed with reference to the price at which the Common Stock was last sold on June 30, 2025. As of March 24, 2026, 53,239,988 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement for its 2026 Annual Meeting of Stockholders, to be filed within 120 days of the Registrant's fiscal year ended December 31, 2025, 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:

- 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 service our existing debt;
- the potential benefits and differentiated profile, FDA approval, commercialization and commercial market for cytisinicline;
- the ability of our third-party manufacturers to receive and maintain FDA approval, and provide sufficient supply of cytisinicline in a timely manner;
- progress and preliminary and future results of any clinical trials;
- timing and plans for the expansion of our focus to develop cytisinicline for additional methods of nicotine dependence beyond the initial proposed indication of smoking;
- 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 fluctuating inflation, interest and tariff rates, the impact of significant political, trade and regulatory developments, potential shutdowns of the U.S. government, 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 this 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:

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

- 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 obtain approval from the FDA or other regulatory agencies to commercialize cytisinicline.
- The development and commercialization of our product candidate is dependent upon securing sufficient quantities of cytisinicline from plant sources, which grow outside of the United States in a limited number of locations.
- We expect to continue to rely on third parties to manufacture cytisinicline. Our commercialization of cytisinicline could be stopped, delayed or made less profitable if we and Sopharma are not able to come to a resolution to our dispute, or if Sopharma or our other manufacturing partners fail to obtain approval of government regulators, fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.
- The FDA may not grant marketing approval of cytisinicline without additional clinical or nonclinical studies, or at all.
- 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 prospects and forecast our financial performance and growth.
- We face substantial competition, and our competitors may discover, develop or commercialize products faster or more successfully than us.

ITEM 1. BUSINESS

OVERVIEW OF OUR BUSINESS AND RECENT DEVELOPMENTS

We are a late-stage clinical specialty pharmaceutical company with the sole mission to address the global nicotine dependence epidemic through the development and commercialization of cytisinicline. There are an estimated 29 million adults in the United States alone who smoke combustible cigarettes and an estimated 17 million adults in the United States who utilize e-cigarettes. Tobacco use is currently the leading cause of preventable death and is responsible for more than eight 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. Our primary focus is to address this global epidemic.

While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain highly addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease. In 2024, 1.6 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 used e-cigarettes. In 2024, the FDA granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. Breakthrough Therapy designation is a process that expedites the development and review of new drugs and biologics that are intended to treat serious or life-threatening conditions and have preliminary clinical evidence indicating substantial improvement over existing therapies.

In October 2025, the FDA awarded cytisinicline for nicotine e-cigarette, or vaping, cessation the Commissioner's National Priority Voucher, or CNPV, as part of the pilot program. A CNPV is granted to product candidates with significant potential to address a major national priority, such as meeting a large unmet medical need, reducing downstream health care utilization or addressing a public health crisis. CNPV recipients will receive a decision from the FDA within one to two months following filing of a complete application for a drug, as well as enhanced communication with review staff throughout the development process prior to their final submission and during the review period. Currently, there are no FDA-approved therapies indicated specifically as an aid for nicotine e-cigarette cessation.

In September 2025, we announced that the FDA accepted for review our New Drug Application, or NDA, for cytisinicline as a treatment for smoking cessation as the first indication in the United States and assigned a Prescription Drug User Fee Act, or PDUFA, targeted action date of June 20, 2026. One third-party manufacturer named in our cytisinicline NDA recently underwent an, non-Achieve related, FDA current Good Manufacturing Practices, or cGMP, inspection and FDA made two observations related to solid oral dose manufacturing, which are being addressed through an ongoing communication with FDA of the company's remedial action plan. While unclear, there is potential for a delay in FDA approval beyond the PDUFA targeted action date of June 20, 2026. We have partnered with a U.S.-based manufacturer, Adare Pharma Solutions, or Adare, to manufacture cytisinicline drug product for potential commercial launch and beyond and have commenced a technology transfer (see Note 11 "Related Party Transactions" in the accompanying consolidated financial statements). We expect the partnership with Adare to provide supply chain redundancy and U.S.-based contingency capacity, help decrease risks related to international importation of pharmaceuticals and reduce costs, including potential tariffs. By establishing U.S. manufacturing with Adare, we expect to decrease our supply chain risk as we progress toward commercial launch of cytisinicline, anticipated to take place in the first-half 2027. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of efficacy, well-tolerated safety profile, and dosing flexibility with a 6 or 12-week regimen, as demonstrated in clinical trials.

Cytisinicline as our Product Candidate

Our product candidate, cytisinicline, is a naturally occurring 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, being both a receptor agonist and antagonist. It is believed to work in treating nicotine dependence for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain by reducing the severity of craving and withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine dependence and has not been approved by the FDA for any indication in the United States.

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 dependence. We have developed an improved dosage, formulation, and simpler treatment schedule. We have an exclusive license and a 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 binds with high affinity to the alpha-4 beta-2, or α4β2, nicotinic acetylcholine receptors in the brain. The α4β2 nicotinic receptor is a well-understood target in dependence. When nicotine binds to this receptor, it causes dopamine to be released in the mid-brain, reinforcing the reward system. This receptor has been implicated in the development and maintenance of nicotine dependence. Cytisinicline is believed to act as a partial agonist/antagonist binding to α4β2 nicotinic receptors in the brain and is thought to have two potential consequences in treating nicotine dependence. First, the partial agonism maintains some release of dopamine (albeit at a very reduced level than that stimulated by nicotine) and therefore reduces nicotine craving, and second, the partial antagonism prevents nicotine binding so that nicotine no longer induces the same pleasure or reward stimulation.

Cytisinicline Opportunity

We are party to a 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 are developing cytisinicline as a drug therapy in treating nicotine dependence for smoking cessation and nicotine e-cigarette cessation which would 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 new, safe and effective smoking cessation treatment. We believe cytisinicline is differentiated from existing smoking cessation treatments given its combination of efficacy, well-tolerated safety profile and dosing flexibility with a 6 or 12-week regimen, as demonstrated in clinical trials. 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 National Institute of Health, or 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 Phase 2 ORCA-1 study and our revisions to the Phase 3 clinical program using a simplified 3 mg tablet administered three times a day, or 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 be reached per protocol definitions 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 exposure 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. These 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 would be sufficient to complete the requirement and enable an NDA submission. In June 2025, we submitted an NDA to the FDA for cytisinicline as a treatment for smoking cessation as the first indication in the United States.

In September 2025, we announced that the FDA accepted for review our ND, for cytisinicline as a treatment for smoking cessation as the first indication in the U.S. and assigned a PDUFA targeted action date of June 20, 2026. One third-party manufacturer named in our cytisinicline NDA recently underwent an, non-Achieve related, FDA cGMP inspection and FDA made two observations related to solid oral dose manufacturing, which are being addressed through an ongoing communication with FDA of the company's remedial action plan. While unclear, there is potential for a delay in FDA approval beyond the PDUFA targeted action date of June 20, 2026. We have partnered with a U.S.-based manufacturer Adare to manufacture cytisinicline drug product for potential commercial launch and beyond and have commenced a technology transfer. We expect the partnership with Adare to provide supply chain redundancy and U.S.-based contingency capacity, help decrease risks related to international importation of pharmaceuticals and reduce costs, including potential tariffs. By establishing U.S. manufacturing with Adare, we expect to decrease our supply chain risk.

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.

In July 2024, we received Breakthrough Therapy designation from the FDA for cytisinicline for nicotine e-cigarette, or vaping, cessation. Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious conditions when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. It provides product sponsors the ability to receive an FDA cross-disciplinary project management team for interactive communications with senior managers and expert reviewers from FDA to expedite the development of a product.

In December 2024, we announced the completion of our end-of-Phase 2 meeting with the FDA to review and receive guidance on our proposed Phase 3 clinical program for a future supplemental NDA submission, or sNDA, to expand cytisinicline for vaping cessation treatment. We obtained FDA agreement on a proposed single Phase 3 study design, including the inclusion/exclusion criteria, primary and secondary efficacy objectives, definition of vaping abstinence with biochemical verification, and other overall study assessments, as well as additional requirements for submitting an sNDA. The FDA agreed that one well-controlled Phase 3 trial, in addition to our completed Phase 2 ORCA-V1 trial and the safety exposure data from our ORCA-OL trial, would be sufficient for a vaping cessation indication as an sNDA. We would target to enroll and complete study evaluations approximately 12 months after study initiation. We may explore additional indications for the treatment of nicotine dependence in the future.

In October 2025, the FDA awarded cytisinicline for nicotine e-cigarette, or vaping, cessation the CNPV as part of the pilot program. The CNPV is granted to products with significant potential to address a major national priority, such as meeting a large unmet medical need, reducing downstream health care utilization or addressing a public health crisis. CNPV recipients will receive a decision from

the FDA within one to two months following filing of a complete application for a drug, as well as enhanced communication with review staff throughout the development process prior to their final submission and during the review period.

Non-Clinical Program

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 exposure 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 an NDA, including two longer-term chronic toxicology studies and two carcinogenicity studies, have been completed and submitted to the FDA.

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 defined 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 escalating 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 dose-limiting 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 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 more 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 Odds Ratio, or 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 also 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%) adverse events, or 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 the 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.

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 2.64 times higher odds, or likelihood, to have quit vaping during the last four weeks of treatment compared to subjects who received placebo (p=0.04). 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 Society for Research on Nicotine and Tobacco, or SRNT, European Annual Meeting in September 2023, the SRNT U.S. Annual Meeting in March 2024, the Society of General Internal Medicine U.S. Annual Meeting in May 2024 and final study results were published in the Journal of the American Medical Association, or JAMA, Internal Medicine in May 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 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.

ORCA-2 subjects had an average age of 52.5 years, smoked a median of 20 cigarettes per day at baseline, and had a median smoking history of 38 years with 4 prior quit attempts.

Cytisinicline was well tolerated with no treatment-related SAEs reported. The most commonly reported AEs (occurring greater than 5% overall in the study) for placebo, 6-week cytisinicline, and 12-week cytisinicline are shown in the following table:

	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%

Completed Phase 3 ORCA-3 Trial

In May 2023, we announced positive topline results for our second Phase clinical trial, ORCA-3. 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. The results of the Phase 3 ORCA-3 trial in 792 adult smokers at 20 clinical sites were:

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 SAEs reported. The most commonly reported (>5% overall) AEs for placebo, 6-week cytisinicline, and 12-week cytisinicline are shown in the following table:

	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%

Company-Sponsored Open Label Clinical Trial for long-term safety effects

Completed Open Label ORCA-OL Trial

The ORCA-OL open-label exposure trial was initiated in May 2024 and was completed in September 2025. The clinical trial enrolled 479 subjects at 29 clinical trial sites across the United States. ORCA-OL was designed to evaluate the long-term safety exposure of 3 mg cytisinicline treatment dosed three times daily in U.S. adults who want to quit smoking or vaping. Subjects received cytisinicline treatment and were monitored for safety events for up to one year. The primary endpoint was frequency of SAEs. Other safety and efficacy outcomes were also collected.

Based on an agreement with the FDA to follow ICH E1 guidance for longer-term safety exposure for pharmaceuticals, the FDA required that we collect six months and one year of cumulative exposure data from a minimum of 300 and 100 subjects, respectively, to submit our cytisinicline NDA and to meet the FDA requirement to provide safety data. We met these goals in January 2025 and April 2025, respectively.

The cumulative one-year exposure data were submitted to the FDA in October of 2025 as part of the 120-day safety update.

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. In 2024, the World Health Organization, or WHO, estimated that there are approximately 1.2 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, and it is estimated that over 1 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 2025, it is estimated that 17 million adults in the United States used e-cigarettes in 2023.

A study that we conducted and that was presented at the 2021 SRNT Annual Meeting, showed results from surveying approximately 500 users of nicotine vaping devices or e-cigarettes with approximately 73% of participants responding 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 dependence.

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 2025, approximately 10.5 million prescriptions were written for smoking cessation treatments 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 minimum 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 (varenicline) after heightened levels of a N-nitrosamine impurity, called N-nitroso-varenicline, which were above the FDA's acceptable daily intake limit, were found in some lots of Chantix tablets. Long-term use of products with N-nitroso-varenicline may be associated with a potential increased cancer risk in humans. In September 2021, Pfizer announced a nationwide recall in the United States of all lots of Chantix and withdrew 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. In February 2026, Pfizer announced that Chantix was re-launched as a cash pay product in the United States under the TrumpRx program.

The vast majority of OTC smoking cessation aids are Nicotine Replacement Therapies, or 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 two decades aimed at aiding individuals in overcoming nicotine dependence. Cytisinicline is positioned to offer a novel solution from existing smoking cessation treatments given its combination of efficacy, well-tolerated safety profile and dosing flexibility with a 6 or 12-week regimen, as demonstrated in clinical trials.

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. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, certain Sopharma patent rights and 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 our 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 coordinate with Sopharma in the defense against any actual or threatened infringement claims with respect to Tabex branded products. 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.

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, extended the term of the Sopharma License Agreement until May 26, 2029, and removed Sopharma's right to terminate the Sopharma License Agreement upon termination or expiration of the Sopharma Supply Agreement.

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 purchase cytisinicline from Sopharma, and Sopharma agrees to supply all such cytisinicline requested by us, and we extended the term to 2037. In addition, Sopharma will manufacture sufficient cytisinicline to meet a forecast for a specified demand of cytisinicline, with the forecast to be updated regularly thereafter. Sopharma has an obligation to obtain and maintain any regulatory and government permits, licenses and approvals that are necessary for Sopharma to manufacture the products to us. 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.

We communicated to Sopharma that we had concerns regarding their ability to pass an FDA pre-approval inspection and that if those concerns were not resolved, we planned to engage third-party manufacturers, and include such manufacturers in our NDA, until such time that Sopharma is able to pass an FDA inspection. In June 2025, we submitted our NDA, which included third-party manufacturers. Sopharma has alleged that our engagement of third-party manufacturers is a breach of our agreement, which we have disputed and have proposed steps to resolve.

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma 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. The contingent consideration liability is measured at fair value in our financial statements (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated financial statements).

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. Through December 31, 2025, we have paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

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

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 $4,800,000(1)
Sopharma AD	$2,000,000(2)

(1) Payable in connection with specific financing, development and commercialization milestones.
(2) Payable contingent on regulatory approval of cytisinicline by the FDA or the European Medicines Agency, 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

It is anticipated that cytisinicline tablets could receive up to seven and a half 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 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. We filed our NDA for cytisinicline in June 2025 and have a PDUFA targeted action date of June 20, 2026. One third-party manufacturer named in our cytisinicline NDA recently underwent an, non-Achieve related, FDA cGMP inspection and FDA made two observations related to solid oral dose manufacturing, which are being addressed through an ongoing communication with FDA of the company's remedial action plan. While unclear, there is potential for a delay in FDA approval beyond the PDUFA targeted action date of June 20, 2026. We have partnered with a U.S.-based manufacturer Adare to manufacture cytisinicline drug product for potential commercial launch and beyond and have commenced a technology transfer. We expect the partnership with Adare to provide supply chain redundancy and U.S.-based contingency capacity, help decrease risks related to international importation of pharmaceuticals and reduce costs, including potential tariffs. By establishing U.S. manufacturing with Adare, we expect to decrease our supply chain risk.

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 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. 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 third-party contract manufacturing organizations, or CMOs, for the manufacturing and clinical packaging supplies of cytisinicline and

have contracted with additional CMOs 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. Cytisinicline-containing plants are harvested annually, dried and processed into cytisinicline. The seeds of these plants in their natural state are highly toxic and the extraction process removes the toxins to produce highly purified cytisinicline. The CMOs source cytisinicline starting material from certain third-party suppliers. We expect to continue stockpiling cytisinicline to meet the projected demand upon commercial launch.

The active pharmaceutical ingredient, or API, manufacturing process utilizes a series of techniques including solvent extraction, recrystallization, filtration, and purification. Critical controls 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.

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, 2025, we control a portfolio of patent families that are owned, co-owned and in-licensed. Those families cover cytisinicline dosing methods, cytisinicline derivatives, cytisinicline salts, methods of cytisinicline extraction, and cytisinicline formulations, among other inventions, in the United States and foreign jurisdictions. As of December 31, 2025, we owned, co-owned or in-licensed over 20 issued patents and over 50 pending patent applications. These patents and applications, if granted, have expiration 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" (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.

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, 2025, we had a total of 28 employees, of whom 11 were engaged in research and development functions, including clinical development, regulatory affairs and manufacturing, and 17 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, and employee safety and wellness. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and an 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 offices are located at 22722 29th Dr. SE Suite 100 Bothell, WA 98021 and 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 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 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. These disclosures reflect our beliefs and opinions as to factors that could materially and adversely affect the Company and our securities in the future. References to past events are provided by way of example only and are not intended to be a complete listing of such events or a representation as to whether or not such factors or similar events have occurred in the past or their likelihood of occurring in the future. This list is not exhaustive, and the order of presentation does not reflect management's determination of priority or likelihood.

Risks Related to Our Financial Condition and Capital Requirements

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

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. There is no assurance that we will obtain financing from other sources. The uncertainty with respect to our operations and the capital markets generally may make it more challenging to raise additional capital on favorable terms, if at all.

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 commercialization.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities and expand our regulatory, manufacturing and commercialization activities. Accordingly, we will need to raise substantial additional capital from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to continue to fund our operations and finance the remaining development and commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development, regulatory review and commercialization efforts.

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 fluctuating inflation, interest and tariff rates and market conditions as well as political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control. Supply chain disruptions and delays as a result of any new tariff

policies or trade restrictions could also negatively impact our cost of materials and production processes. For example, the United States has announced tariffs on many goods imported from foreign countries. In addition, there are currently headlines and discussions concerning potential increased tariffs for pharmaceutical products, which may impact our supply chain and create uncertainty in the broader pharmaceutical industry.

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 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 uncertainty in various sectors, including capital markets. 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 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 success of our commercialization activities;
- the progress and results of our research and development programs;
- the repayment or conversion of our outstanding debt;
- 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 would be forced to delay, scale back or eliminate some of our commercialization and R&D activities or other operations and potentially delay commercialization and product development in an effort to provide sufficient funds to continue our operations. Additionally, if we are unsuccessful in raising additional funds, we may decide to explore a range of strategic alternatives to maximize stakeholder value, which may include, without limitation, a sale of assets and/or the initiation of bankruptcy proceedings. 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.

On July 25, 2024, we entered into a contingent convertible debt agreement, or New Debt Agreement, with Silicon Valley Bank, or SVB, a division of First-Citizens Bank & Trust Company, or FCB, in its capacity as administrative agent and collateral agent, and FCB, as a lender, or Lender. As of December 31, 2025 the principal amounts due under our debt instruments totaled $15.0 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. Our outstanding debt matures on December 1, 2027, subject to certain potential extensions. 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 New 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 our outstanding debt 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 Lender to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Lender could declare a default under the New Debt Agreement upon the occurrence of any event that the Lender interprets as a material adverse change as defined under the New 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 Lender 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, our outstanding debt 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 Silicon Valley Bank, or 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. Our outstanding debt 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 late-stage clinical 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:

- establish a sales, marketing, and distribution infrastructure to commercialize cytisinicline;
- continue the clinical development of 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;

- experience delays in the development of our cytisinicline candidate, including delays in clinical trials and delays in regulatory review;
- initiate additional non-clinical, clinical, or other trials or studies for cytisinicline;
- make milestone, royalty or other payments under third-party license and/or supply agreements;
- seek to establish, maintain, protect, and expand our intellectual property portfolio;
- seek to discover, identify, assess, acquire, and/or develop other product candidates;
- 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:

- 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;
- completing research and development of cytisinicline;
- 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 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 New 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 obtain approval from the FDA or other regulatory agencies to commercialize cytisinicline.

We are currently dependent on the potential development and FDA approval of a single product candidate, cytisinicline. We are still developing and seeking regulatory approval for 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. In September 2025, we announced that the FDA accepted for review our NDA for cytisinicline as a treatment of nicotine dependence for smoking cessation as the first indication in the United States and assigned a Prescription Drug User Fee Act, or PDUFA, targeted action date of June 20, 2026. Deficiencies identified at the site of the third-party manufacturer designated in our NDA may delay approval of our NDA beyond the assigned PDUFA targeted action date of June 20, 2026. We may receive a complete response letter, or CRL, rather than approval of the NDA at the conclusion of the FDA's review. The contents of such CRL could be made public by the FDA and could result in reputational harm to our company and cytisinicline, result in litigation, or result in a delay or the inability to commercialize cytisinicline. 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.

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

The therapeutic component of our product candidate, cytisinicline, is derived from plants in the Faboideae subfamily of plant species, which grow in the mountains of Southern Europe, Russia, China 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. There can be no assurances that plants 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.

The FDA may not 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 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 dependence by interacting with nicotine receptors in the brain, reducing the severity of nicotine craving and withdrawal symptoms through agonistic effects on nicotine receptors and reducing the reward and satisfaction associated with nicotine through antagonistic properties. Cytisinicline has been studied for smoking cessation 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. Cytisinicline has also been evaluated for vaping cessation in a company-sponsored, randomized, multicenter, double-blind, placebo-controlled Phase 2 clinical study involving 160 adults who used nicotine e-cigarettes.

The FDA advised us 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, which we refer to as ORCA-OL, evaluating the long-term safety effects of cytisinicline would be sufficient to complete the requirement and enable an NDA submission. The ORCA-OL open-label exposure trial was initiated in May 2024 and was completed in September 2025. The clinical trial enrolled 479 subjects at 29 clinical trial sites across the United States. Safety data, from the ORCA-OL trial, on over 300 participants with at least six months of cumulative cytisinicline exposure was included in our NDA submission in June 2025 and on over 100 participants receiving at least one year of cumulative cytisinicline exposure was submitted to the FDA in October 2025 as part of the 120-day safety update. In September 2025, we announced that the FDA accepted for review our NDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults and assigned a PDUFA targeted action date of June 20, 2026. Deficiencies identified at the site of the third-party manufacturer designated in our NDA may delay approval of our NDA beyond the assigned PDUFA targeted action date of June 20, 2026. 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 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 assessments may not be acceptable for the proposed indication;
- 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.

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

Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. 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 will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

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

- disruptions to our supply chain for the cytisinicline required for our clinical trials;
- patients terminating enrollment in our clinical trials;
- adverse events or tolerability issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;
- occurrence of adverse events associated with our product candidate;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of cytisinicline;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in ongoing or other planned indications for cytisinicline;
- 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 in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for cytisinicline could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to cytisinicline, we may need to conduct additional non-clinical trials, or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could 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.

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:

- 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;
- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- 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;
- damage to our reputation and the reputation of our products and our technology; and
- diversion of management's attention from our business.

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 suppliers of cytisinicline, could be adversely affected if they experience a shortage of fresh water due to droughts or if they experience 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, which could have a material adverse effect on our business, financial condition and results of operations.

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

We may 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 September 2025, we announced that the FDA accepted for review our NDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults and assigned a PDUFA targeted action date of June 20, 2026. Deficiencies identified at the site of the third-party manufacturer designated in our NDA may delay approval of our NDA beyond the assigned PDUFA targeted action date of June 20, 2026. Even with the acceptance of our NDA by the FDA, we cannot predict whether the results of our clinical trials and/or the data from our research and clinical approaches included in the NDA will be sufficient to demonstrate the safety and efficacy of cytisinicline for approval from the FDA for the proposed indication 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.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Disruptions at the FDA may slow the time necessary for new products to be reviewed and/or approved, which would adversely affect our business. In addition, there is substantial uncertainty regarding new initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.

Disruptions at the FDA may slow the time necessary for new products to be reviewed and/or approved, which would adversely affect our business. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. If any legislation, executive orders, or lapses in agency funding impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similar consequences would also result in the event of another significant shutdown of the federal government. For example, in 2024 and 2025, the U.S. government was on the verge of a shutdown or shut down several times, and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

FDA-regulated industries, such as ours, face uncertainty with regard to the regulatory environment we will face as we proceed with research, development and commercialization. Some of these efforts have manifested to date as efforts to reduce the size of the federal government, including large-scale reductions in force at the FDA. The loss of key personnel at the FDA, including those in leadership positions, is likely to impact operations at the FDA, which could result in, among other things, delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development, longer review times and delays in obtaining regulatory approvals for our product candidates. There remains general uncertainty regarding future activities. New executive orders, regulations, policies or guidance could be issued or promulgated that adversely affects us or creates a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance, there could be a material adverse effect on us and our business.

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 took 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.

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, and our third-party contract manufacturers, 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 our contract manufacturers fail to maintain cGMP compliance or fail inspections with the FDA and other regulators, then our business could be severely 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. 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.

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.

Moreover, our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition, results of operations and prospects. Our employees could also inappropriately utilize artificial intelligence, or AI, in connection with their

social media communications, introducing another potential source of reputational damage or other potential legal or financial exposure.

A Breakthrough Therapy designation by the FDA and our receipt of a CNPV may not lead to a faster development or regulatory review or approval process for the nicotine e-cigarette/vaping cessation indication and it does not increase the likelihood that our product candidates will receive marketing approval.

The FDA has granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development but does not guarantee a more efficient path.

The FDA has also awarded us a CNPV for cytisinicline for vaping cessation. While the CNPV is designed to provide enhanced communications with the FDA and expedite its review of a therapy, we would still be required to commence the voucher process within the two-year time period set by the FDA, which will require significant time and expense. In addition, this time limit may lapse before we are able to meet the requirements, which would result in us losing the CNPV benefit of an expedited review for vaping cessation.

Our receipt of Breakthrough Therapy designation and a CNPV for cytisinicline may not result in a faster development process, review or approval and does not assure ultimate approval by the FDA. In addition, when a product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification.

Risks Related to our Business Operations

It is difficult to evaluate our current business, predict our 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, commercial and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. We expect to need additional scientific, technical, operational, financial and other personnel. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Richard Stewart, Craig Donnelly, Erik Atkisson, Jaime Xinos, Mark Oki and Mark Rubinstein. In addition, although we have entered into employment agreements with each of Mr. Stewart, Mr. Donnelly, Mr. Atkisson, Ms. Xinos, Mr. Oki and Dr. Rubinstein, 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 will need to expand our organization as we prepare for potential commercialization of cytisinicline, 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 do not currently have a commercial infrastructure, and we may not be able to successfully develop a commercial infrastructure to support the commercialization of cytisinicline on the timeline needed, or at all. Commercialization requires significantly greater financial and organizational resources, which may not be available to us. 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 and commercialization requires significant capital expenditure 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 or commercialize plans, 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 and commercialization.

We plan to 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.

We plan to invest in the research and development of new indications for cytisinicline to address nicotine dependence 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 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.

In efforts to innovate and optimize operational efficiency, certain third parties with whom we work may integrate AI into various aspects of their work with us. While we do not currently utilize AI tools in a significant way, we may in the future integrate AI into various projects, including as a component of our commercialization strategy. While AI presents opportunities for enhanced productivity and innovation, it also introduces inherent risks, including legal and regulatory, that could adversely impact our business and reputation. Proper use of AI can lead to improved decision-making, cost reduction, and competitive advantage. However, improper use, including algorithmic biases, ethical considerations, data privacy issues, unknown or zero-day software vulnerabilities, and potential regulatory non-compliance, by our employees or third parties with whom we work could result in reputational damage, legal liabilities, and financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs. We are committed to implementing robust governance and control mechanisms to mitigate these risks, but there can be no assurance that such measures will adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties to manufacture cytisinicline. Our commercialization of cytisinicline could be stopped, delayed or made less profitable if we and Sopharma are not able to come to a resolution to our dispute, or if Sopharma or our other manufacturing partners fail to obtain approval of government regulators, fail to provide us with sufficient quantities of product or fail 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. Our current supply agreement with Sopharma expires on July 28, 2037, unless extended by agreement between us and Sopharma. We may encounter technical difficulties or delays in the transfer of cytisinicline manufacturing on a commercial scale to other third-party manufacturers or encounter difficulties and delays in identifying other third-party manufacturers beyond our current manufacturers. We may be unable to enter into agreements for commercial supply with third-party manufacturers on acceptable terms, or at all. If and when product sales for cytisinicline commence and grow, cytisinicline will require production processes to be scaled up. We will be dependent on external manufacturers and suppliers to ensure that their manufacturing processes can be scaled up adequately such that we are able to supply the market. If any of our key suppliers are unable or unwilling to scale up production, or we otherwise experience a product shortfall, any such product shortfall could delay commercialization of cytisinicline and impair sales, and our business, financial condition and results of operations could be materially adversely affected.

Third-party manufacturers, or CMOs, 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. Failure by CMOs to pass a pre-approval inspection by the FDA may require us to pursue alternative manufacturers, which could result in delay in review or approval or our NDA and commercialization, additional costs or other adverse impacts. Additionally, failure by CMOs to pass a pre-approval inspection by the FDA or to otherwise comply with applicable regulations may result in delays and interruptions to our product candidate supply, or additional costs, while we seek to secure another supplier that meets all regulatory requirements. For example, 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 in a timely manner or at all. We have concerns regarding Sopharma's ability to pass an FDA pre-approval inspection. We plan to engage third-

party manufacturers, or CMOs, to manufacture cytisinicline and have included a CMO in our NDA in the event that Sopharma is unable to meet inspection requirements of the FDA. However, we are aware of uncertainties regarding the ability of the CMO named in our NDA to maintain approval by the FDA. If the CMO named in our NDA is not able to maintain FDA approval, approval of our NDA and ultimate commercialization may be delayed. Additionally, if our concerns regarding Sopharma are not resolved, we plan to engage third-party manufacturers until such time that Sopharma is able to pass an FDA inspection. Sopharma has alleged that our engagement of third-party manufacturers is a breach of our agreement, which we have disputed and have proposed steps to resolve the parties' dispute. In the event we are unable to resolve our ongoing dispute with Sopharma, such dispute may result in litigation, additional costs or delays in activities relating to our NDA or ultimate commercialization.

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

- Sopharma and other CMOs 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 other CMOs may not be able to execute our manufacturing procedures appropriately;
- Sopharma and other CMOs 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 other CMOs 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 other CMOs in the manufacturing process for cytisinicline;
- we do not own all the intellectual property rights to cytisinicline, and Sopharma and other CMOs could license such rights to third parties or begin supplying other third parties with cytisinicline; and
- Sopharma and other CMOs 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.

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 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, manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or political instability in the countries in which they conduct their operations. 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 of a nitrosamine impurity, called N-nitroso-varenicline, which were above the FDA's acceptable daily intake limit, were found in some lots of Chantix pills. Long-term use of products containing N-nitroso-varenicline may be associated with a potential increased cancer risk in humans. In September 2021, Pfizer announced a nationwide recall in the United States of all lots of Chantix and also withdrew the product in other countries around the globe. In February 2026, Pfizer announced that Chantix would be made available in the United States. We have undertaken a review of cytisinicline in accordance with regulatory guidance to assess the risk of the presence of nitrosamines 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 and our CMOs may also be impacted by new legislation and regulations relating to the manufacture of medical products. For example, legislation has been introduced and passed in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies. Certain members of Congress have advocated for the

use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation.

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 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

If we are unable to establish distribution, marketing, and sales capabilities, we may not be successful in commercializing cytisinicline, if approved.

To achieve commercial success for cytisinicline, if approved, we will need to establish or outsource critical distribution, marketing and sales capabilities.

We plan to establish necessary internal commercial infrastructure and engage third parties to build certain commercial capabilities to market cytisinicline. There are risks involved with entering into arrangements with third parties to perform these services. Furthermore, we have entered into a partnership with Omnicom to support the commercial launch of cytisinicline in the United States, which requires financial commitments in advance of approval and may result in disruption of our commercialization efforts if disputes or other issues arise in our relationship with Omnicom. If the commercial launch of cytisinicline is delayed or does not occur for any reason, including failure to receive marketing approval from the FDA, we would have prematurely or unnecessarily incurred these commercialization expenses.

Factors that may inhibit our efforts to commercialize cytisinicline, if approved, on our own include:

- our inability to recruit and retain qualified commercial experts for core commercial functions, or our inability to maintain adequate staffing for outsourced sales and marketing activities;
- the inability of sales representatives to obtain access to physicians or persuade adequate numbers of physicians to prescribe cytisinicline;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors for cytisinicline;
- the inability to price cytisinicline at a sufficient price point to ensure appropriate insurance coverage and an attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute cytisinicline to segments of the patient population;
- the lack of complementary product candidates to be offered by us, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and outsourcing critical commercial functions.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates outside of the United States or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish distribution, marketing and sales capabilities successfully in collaboration with third parties, we will not be successful in commercializing our product candidates.

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 if we receive 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.

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. 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. 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. 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.

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.

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.

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.

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.

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 our 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.

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.

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.

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 CMOs, 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.

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

Although our current efforts focus on clinical testing, approval, and potential commercialization of cytisinicline, our sole product candidate, the success of our business may also 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.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations that can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We currently have an agreement with Sopharma to supply cytisinicline, and we may engage third parties for clinical trials outside of the United States, to sell our products abroad or provide other services in connection with commercialization, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described

above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Risks Related to our Intellectual Property

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 can 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 and dosing regimens 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 obtain regulatory approvals for cytisinicline or other product candidates, and delays or failures to obtain such approvals;
- our ability or the ability of 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 to establish a commercial infrastructure and complete other pre-commercialization and commercialization tasks to necessary to successfully commercialize cytisinicline should it be approved by the FDA;
- 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 federal or global health policies, legislation or the review and oversight functions of federal health regulatory bodies;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions and geopolitical conditions, including fluctuating inflation, interest and tariff 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;
- sales of our common stock by 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 July 2024, we entered into the New Debt Agreement with the Lenders for term loans of up to $20.0 million, which included term loans of up to $10.0 million available upon the occurrence of certain events as provided for in the New Debt Agreement and further described below, or the New Convertible Term Loan. The New Convertible Term Loan matures on June 1, 2028. The first tranche of the New Convertible Term Loan, which was advanced on July 25, 2024, has an aggregate original principal amount of $10.0 million. The Lender made available to us, upon our request: (a) on or prior to October 31, 2025, a second tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million in the event that we received written notice that the FDA had accepted for filing our NDA with respect to cytisinicline for a smoking cessation indication, or the Additional Term Loan Event I, and (b) on or prior to December 31, 2025, a third tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million, subject to the Lender's sole discretion.

In October 2025, pursuant to the New Debt Agreement and following the occurrence of the Additional Term Loan Event I as described therein, we drew down on the second tranche of the New Convertible Term Loan for an additional $5.0 million. We did not draw down on the third tranche of the New Convertible Term Loan and it expired and became unavailable on December 31, 2025.

Subject to certain terms and conditions, the Lenders may convert all or any part of the outstanding New 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 (i) for the first tranche of $10.0 million, $7.00 per share, subject to customary anti-dilution adjustments and (ii) for the second tranche of $5.0 million each, the greater of (x) $4.854 per share, subject to customary anti-dilution adjustments, and (y) the lower of (a) 150% of the average of the closing sale price of our common stock during the 10 trading days preceding the effective date of such tranche and (b) 150% of the closing sale price of our common stock on the trading day immediately preceding the effective date of such tranche. Additionally, all outstanding amounts under the New 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 (i) for the first tranche, equal to or greater than $24.00 for 30 consecutive trading days prior to such date and (ii) for the second tranche, three times the applicable conversion price for such tranche, in each case, for the 30 consecutive trading days prior to such date. We are aware that there can be no assurance that the New Convertible Term Loan will be available to us for borrowing nor whether the Lender will be willing to work with us on any modifications to the current New Convertible Term Loan or the New Debt Agreement.

As of December 31, 2025, there were 2,730,211 shares of our common stock subject to outstanding options and 1,084,330 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, 2025, there were approximately 20,398,307 shares of our common stock subject to outstanding warrants to purchase common stock, with a weighted average exercise price of $3.30 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 June 2025, we entered into an underwriting agreement, pursuant to which we sold and issued warrants to purchase up to 16,766,666 shares of our common stock (or pre-funded warrants), with an exercise price of $3.00 per share (or $2.999 per pre-funded warrant), or the June 2025 Public Offering. If additional shares are issued upon exercise of these 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 New 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 New 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 New 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.

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. For example, pursuant to the June 2025 Public Offering, we sold and issued 16,419,896 shares of our common stock and accompanying common warrants purchase up to 16,766,666 million shares of common stock, or pre-funded warrants to purchase shares of our common stock in lieu thereof, at the public offering price of $3.00 per share and accompanying warrant.

Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

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

We are currently a "smaller reporting company" as defined in the 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.

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.

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.

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.

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.

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, for our 2022 to 2024 tax years, the Tax Cuts and Jobs Act required research and experimental expenditures to be capitalized and amortized ratably over a five-year period for U.S. expenditures. Any such expenditures attributable to research conducted outside the United States were required to be capitalized and amortized over a 15-year period. Beginning with our 2025 tax year, tax legislation has restored immediate deductibility of U.S. expenditures, while foreign expenditures will continue to 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, or that of our suppliers, could be enacted by any governmental authority, including foreign tax authorities. 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 quarterly, 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 Vice President of Information Technology who has served in various roles managing information technology and information security for over twenty-five years and reports directly to our Chief Financial 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 business offices located in Bothell, Washington and Vancouver, British Columbia.

We have leased an office space in Vancouver, British Columbia since November 2018. The leased office space is approximately 2,367 square feet and the annual rent is approximately $0.1 million. On December 9, 2024, we entered into an agreement to extend the lease for another two-year term, which commenced on February 1, 2025.

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. On May 10, 2025, we entered into an agreement to extend the lease for another six-month term, which commenced on September 1, 2025. The annualized rent is approximately $17,000.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Our common stock first began trading on the Nasdaq National Market under the symbol "SNUS" on October 12, 1995. In connection with a corporate transaction and name change, our common stock commenced trading on the Nasdaq Capital Market under the stock symbol "OGXI," effective August 21, 2008. Following the completion of 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 20, 2026, there were approximately 9 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, 2025 were made by us or on our behalf.

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, 2024 compared to the year ended December 31, 2023 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, 2024 filed with the SEC on March 11, 2025.

Overview

We are a late-stage clinical specialty pharmaceutical company with the sole mission to address the global nicotine dependence epidemic through the development and commercialization of cytisinicline. There are an estimated 29 million adults in the United States alone who smoke combustible cigarettes and an estimated 17 million adults in the United States who utilize e-cigarettes. Tobacco use is currently the leading cause of preventable death and is responsible for more than eight 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. Our primary focus is to address this global epidemic.

While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain highly addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease. In 2024, 1.6 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 used e-cigarettes. In 2024, the FDA granted Breakthrough Therapy designation for cytisinicline for nicotine e-cigarette, or vaping, cessation. Breakthrough Therapy designation is a process that expedites the development and review of new drugs and biologics that are intended to treat serious or life-threatening conditions and have preliminary clinical evidence indicating substantial improvement over existing therapies.

In October 2025, the FDA awarded cytisinicline for nicotine e-cigarette, or vaping, cessation the Commissioner's National Priority Voucher, or CNPV, as part of the pilot program. A CNPV is granted to product candidates with significant potential to address a major national priority, such as meeting a large unmet medical need, reducing downstream health care utilization or addressing a public health crisis. CNPV recipients will receive a decision from the FDA within one to two months following filing of a complete application for a drug, as well as enhanced communication with review staff throughout the development process prior to their final submission and during the review period. Currently, there are no FDA-approved therapies indicated specifically as an aid for nicotine e-cigarette cessation.

Cytisinicline is a natuarlly occuring alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to work in treating nicotine dependence for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain by reducing the severity of craving and withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for treatment of nicotine dependence. In September 2025, we announced that the FDA accepted for review our New Drug Application, or NDA, for cytisinicline as a treatment for smoking cessation as the first indication in the United States and assigned a Prescription Drug User Fee Act, or PDUFA, targeted action date of June 20, 2026. One third-party manufacturer named in our cytisinicline NDA recently underwent an, non-Achieve related, FDA current Good Manufacturing Practices inspection and FDA made two observations related to solid oral dose manufacturing, which are being addressed through an ongoing communication with FDA of the company's remedial action plan. While unclear, there is potential for a delay in FDA approval beyond the PDUFA targeted action date of June 20, 2026. We have partnered with a U.S.-based manufacturer, Adare Pharma Solutions, or Adare, to manufacture cytisinicline drug product for potential commercial launch and beyond and have commenced a technology transfer (see Note 11 "Related Party Transactions" in the accompanying consolidated financial statements). We expect the partnership with Adare to provide supply chain redundancy and U.S.-based contingency capacity, help decrease risks related to international importation of pharmaceuticals and reduce costs, including potential tariffs. By establishing U.S. manufacturing with Adare, we expect to decrease our supply chain risk as we progress toward commercial launch of cytisinicline, anticipated to take place in the first-half 2027.

We believe cytisinicline represents a unique opportunity to significantly impact global health by addressing the considerable unmet need among millions of smokers and e-cigarettes users. We believe cytisinicline is differentiated from existing smoking cessation

treatments given its combination of efficacy, well-tolerated safety profile and dosing flexibility with a 6 or 12-week regimen, as demonstrated in clinical trials.

We believe we will be able to commercialize independently in the U.S. market by focusing our marketing and sales efforts on highly targeted prescriber and patient audiences. We are planning to launch by utilizing a well-established marketing technology infrastructure and embedding Artificial Intelligence, or AI, tools to enhance targeting, decision making, and performance metrics. Launch planning and readiness activities are underway, leveraging our integrated agency partnership with Omnicom, with teams established for key functional areas including market access, medical education, prescriber and patient marketing, and digital infrastructure. Additionally, field-based and virtual sales representatives will supplement digital promotional efforts.

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 $54.6 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $260.2 million, cash, cash equivalents and marketable securities balance of $36.4 million and a positive working capital balance of $30.8 million. During the year ended December 31, 2025, net cash used in operations was $49.5 million.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. For additional information, see the section titled "—Liquidity, Capital Resources and Going Concern."

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. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, certain Sopharma patent rights and the trademark Tabex in all territories described in the Sopharma License Agreement. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-single digit percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. We have agreed to coordinate with Sopharma in the defense against any actual or threatened infringement claims with respect to Tabex branded products. 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.

We communicated to Sopharma that we had concerns regarding their ability to pass an FDA pre-approval inspection and that if those concerns were not resolved, we planned to engage third-party manufacturers, and include such manufacturers in our NDA, until such time that Sopharma is able to pass an FDA inspection. In June 2025, we submitted our NDA, which included third-party manufacturers. Sopharma has alleged that our engagement of third-party manufacturers is a breach of our agreement, which we have disputed and have proposed steps to resolve.

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma 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, 2025, the fair value of the contingent consideration was estimated to be $1.6 million as compared to $1.1 million as of December 31, 2024 (see Note 2 "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated financial statements). We recognized losses of $0.4 million and $0.6 million for the years ended December 31, 2025 and 2024 respectively.

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 paid an initial amount of $37,500 and agreed to pay additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones, in addition to amounts under the original University of Bristol License Agreement. 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 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. Through December 31, 2025, we have paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for clinical trials, manufacture of product, 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.

Our R&D expenses will vary materially between quarters based on the timing of our clinical trials. 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 personnel costs related to executive, finance and accounting, and other administrative functions, as well as consulting costs, including commercial, corporate communications, 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, 2025 and 2024

Research and Development Expenses

Our R&D expenses are devoted to our ongoing clinical development program, cytisinicline. R&D expenses for the years ended December 31, 2025 and 2024 were $23.0 million and $22.8 million, respectively. The increase in 2025 as compared to 2024 was primarily due to higher employee costs from increased headcount and higher manufacturing and supply chain costs associated with commercial launch preparation, including purchase of raw cytisinicline inventory expensed to R&D prior to regulatory approval. This was partially offset by lower clinical trial costs associated with the wind down of the ORCA-OL trial which was completed at the end of September 2025.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2025 and 2024 were $31.9 million and $16.3 million, respectively. The increase in 2025 as compared to 2024 was primarily due to higher commercial launch preparation costs, which were $12.3 million in 2025 as compared to $1.2 million in 2024, and a $2.7 million increase in stock-based compensation expense in 2025 as compared to 2024.

Interest Income

Total interest income for the years ended December 31, 2025 and 2024 was $1.5 million and $2.4 million, respectively. The decrease in interest income for the year ended December 31, 2025 as compared to 2024 was primarily due to lower average cash balances throughout 2025 and lower interest rates.

Interest Expense

Total interest expense for the years ended December 31, 2025 and 2024 was $0.8 million and $2.2 million, respectively. The decrease in interest expense for the year ended December 31, 2025 as compared to the same period in 2024 was due to a lower principal balance on our New Convertible Term Loan, relative to the prior contingent convertible debt agreement with the Lenders, that bears only a monthly interest as a result of the debt refinancing under the New Debt Agreement (such terms as defined in "Liquidity and Capital Resources" below).

Change in fair value of 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 cytisinicline's current clinical development phase and the remaining requirements for regulatory approval. 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 (see Note 6 "Fair Value Measurements—Fair Value of Sopharma Share Purchase Agreement Contingent Consideration" in the accompanying consolidated financial statements).

For the years ended December 31, 2025 and 2024 we recognized losses of $0.4 million and $0.6 million, respectively.

Loss on extinguishment of 2023 Silicon Valley Bank convertible term loan

The debt refinancing under the New Debt Agreement was recognized as an extinguishment of debt under Accounting Standards Update, or ASU, 470-50. The difference between the reacquisition price and carrying value was recognized on the Consolidated Statement of Loss as a loss on extinguishment of debt.

For the year ended December 31, 2024 we incurred a loss on extinguishment of debt of $0.3 million.

Liquidity, Capital Resources and Going Concern

We have incurred an accumulated deficit of $260.2 million through December 31, 2025, and we expect to incur substantial additional losses in the future as we operate our business and continue or expand our regulatory, manufacturing, commercialization and other 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, 2025, we had cash, cash equivalents and marketable securities of $36.4 million and a positive working capital balance of $30.8 million. For the year ended December 31, 2025, net cash used in operations was $49.5 million.

We have historically financed our operations through equity and debt financings and government grants. As a late-stage clinical specialty pharmaceutical 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 clinical development and commercialization activities.

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

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. While we have historically financed our operations through equity offerings, debt financings, and government grants, the timing and amount of future financings may be impacted by macroeconomic conditions including uncertainty in the capital markets. There can be no assurance that financing from these or other sources will be available to us in the future. Without additional funds, we would be forced to delay, scale back or eliminate some of our commercialization and research and development, or R&D, activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our commercialization and development goals would be adversely affected.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Accordingly, we will need to raise substantial additional capital from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to continue to fund our operations and finance the remaining development and commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace of our commercialization activities and the pace and results of our clinical development efforts. The uncertainty with respect to our operations and the market generally may also make it challenging to raise additional capital on favorable terms, if at all. In addition, current macroeconomic conditions have caused uncertainty in various sectors, including the capital markets. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to prepare for commercialization and develop our product candidate. We expect our expenses to substantially increase over time in connection with our development, particularly as we prepare our commercialization activities and advance our product candidate in clinical development.

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 efforts to achieve regulatory approval, commercialization activities, and of clinical development programs.

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

We did not have during the periods presented, and we do not currently have, any commitments or obligations, including contingent obligations, other than the Sopharma Contingent Consideration, arising from arrangements with unconsolidated entities or persons that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Convertible Debt

On July 25, 2024, we entered into a contingent convertible debt agreement, or New Debt Agreement, with Silicon Valley Bank, or SVB, a division of First-Citizens Bank & Trust Company, or FCB, in its capacity as administrative agent and collateral agent, and FCB, as a lender, or Lender, pursuant to which the Lender provided term loans having an aggregate original principal amount of $10.0 million, with additional term loans of up to $10.0 million available upon the occurrence of certain events as provided for in the New

Debt Agreement and further described below, or New Convertible Term Loan. Our obligations under the New Debt Agreement are secured by substantially all of our assets, other than intellectual property.

The New Convertible Term Loan matures on June 1, 2028. The first tranche of the New Convertible Term Loan, which was advanced on July 25, 2024, has an aggregate original principal amount of $10.0 million. The Lender made available to us, upon our request: (a) prior to October 31, 2025, a second tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million in the event that we received written notice that the FDA had accepted for filing our NDA with respect to cytisinicline for a smoking cessation indication, or the Additional Term Loan Event I, and (b) on or prior to December 31, 2025, a third tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million, subject to the Lender's sole discretion.

In October 2025, pursuant to the New Debt Agreement and following the occurrence of the Additional Term Loan Event I as described therein, we drew down on the second tranche of the New Convertible Term Loan for an additional $5.0 million. We did not draw down on the third tranche of the New Convertible Term Loan and it expired and became unavailable on December 31, 2025.

Interest is calculated on the outstanding principal amount of the New Convertible Term Loan at a floating rate per annum equal to the greater of (i) 7.0% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears and shall be payable on the earlier to occur of (x) the first day of the first month following any extension of credit by the Lender for our credit, (y) the date of any prepayment pursuant to the New Debt Agreement, or (z) the maturity date. The New Convertible Term Loan will be "interest-only" until June 30, 2026.

Subject to certain terms and conditions, the conversion feature grants the Lender or, pursuant to an assignment, any designee thereof, or Conversion Right Holders, the right to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to $7.00, subject to customary adjustment provisions. The Conversion Right Holders have the further right to convert part or all of the outstanding principal amount of the second tranche of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to the greater of (i) $4.854, subject to customary adjustment provisions, and (ii) the lower of (a) 150% of the average of the closing sale price of our common stock during the 10 trading days preceding the effective date of such tranche and (b) 150% of the closing sale price of our common stock on the trading day immediately preceding the effective date of such tranche.

The conversion rights may be exercised at each Conversion Right Holder's option any time prior to repayment of the New Convertible Term Loan; provided, however, that the Conversion Right Holders will not be permitted to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan without the agreement of the relevant Conversion Right Holder and us if the sum of the amount of debt to be converted; and the aggregate amount of debt previously converted pursuant to any such voluntary conversion, divided by the aggregate of all debt that is then outstanding or that has been repaid other than by conversion exceeds 50%.

Additionally, the outstanding principal of the New Convertible Term Loan, plus accrued and unpaid interest, will automatically be converted into shares of our common stock at the applicable conversion price on such date if any, when the closing price per share of our common stock has been equal to or greater than (a) in the case of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, $24.00 or, (b) in the case of the outstanding principal amount of the second tranche of the New Convertible Term Loan, plus accrued and unpaid interest, three times the applicable conversion price, in each case for the thirty consecutive trading days prior to such date, and the Liquidity Conditions (as defined in the New Debt Agreement) have been satisfied.

The New Convertible Term Loan may be repaid at our election and upon notice to the Agent (as defined in the New Debt Agreement) by paying the Lender an amount equal to (i) a prepayment fee equal to (a) 3.0% of the aggregate outstanding principal balance if such prepayment occurs on or prior to the first anniversary of the New Convertible Term Loan, (b) 2.0% of the aggregate outstanding principal balance if such prepayment occurs after the first anniversary, but on or prior to the second anniversary, of the New Convertible Term Loan or (c) 1.0% of the aggregate outstanding principal balance if such prepayment occurs after the second anniversary of the New Convertible Term Loan and before the maturity date; (ii) 4.0% of the original aggregate principal amount of the New Convertible Term Loan and (iii) all other sums due and payable under the New Convertible Term Loan.

The New 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 New Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lender may not

engage in any short sales of, or other hedging transactions in, our common stock while any amounts are outstanding under the New Debt Agreement. As of December 31, 2025, we are in compliance with all covenants under the New Debt Agreement.

In connection with the New Debt Agreement, we entered into a Registration Rights Agreement, or RRA, with the Lender, pursuant to which we registered for resale shares of our common stock issuable to the Conversion Right Holders upon the conversion of outstanding debt under the New Debt Agreement. Our obligations under the RRA will terminate with respect to a holder of applicable registrable securities if, as of the date we would be required to provide written notice of such registration, (x) the aggregate number of registrable securities then issued and issuable to such holder and to such holder's affiliates, together with all other shares then held beneficially and/or of record by such holder and its affiliates, does not exceed 7.0% of our then-total shares issued and outstanding (calculated including all such registrable securities and other shares), or (y) we and such holder mutually reasonably agree that all registrable securities then issued and issuable to such holder and its affiliates may then be sold by such holder without the requirement to be in compliance with Rule 144 promulgated under the Securities Act, or Rule 144, and otherwise without restriction or limitation pursuant to Rule 144.

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 28, 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 were immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof and expired in October 2025 on the date 30 days after our public disclosure of the acceptance of an NDA filing for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence. The shares of common stock issuable upon exercise of the warrants (or pre-funded warrants, as applicable) were subsequently registered pursuant to our registration statement on Form S-3, which was declared effective on May 6, 2024.

The registered direct offering raised total gross proceeds of approximately $60.0 million, and after deducting approximately $3.9 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.1 million.

June 2025 Public Offering

On June 26, 2025, we entered into an underwriting agreement, or Underwriting Agreement, with Citizens JMP Securities, LLC and Raymond James & Associates, Inc., or the Underwriters, as representatives of the underwriters, pursuant to which we agreed to issue and sell to the Underwriters 15,000,000 shares of our common stock, or the Shares, and accompanying common warrants, or Accompanying Warrants, to purchase up to 15,000,000 shares of common stock, or Warrant Shares, or pre-funded warrants to purchase shares of our common stock in lieu thereof, or Pre-Funded Warrants.

The Shares and Accompanying Warrants were sold collectively at the public offering price of $3.00 per Share and Accompanying Warrant, less underwriting discounts and commissions. Pursuant to the Underwriting Agreement, we also granted the Underwriters a 30-day option to purchase up to an additional 2,250,000 Shares and/or up to an additional 2,250,000 Accompanying Warrants at the same public offering price per Share and Accompanying Warrant, less underwriting discounts and commissions. On June 28, 2025, the Underwriters exercised their option in part to purchase an additional 1,766,666 Accompanying Warrants. On July 25, 2025, the Underwriters exercised their option in part to purchase an additional 1,419,896 Shares.

Each Accompanying Warrant is exercisable, at the purchaser's election, for either Warrant Shares at an exercise price of $3.00 per share or for Pre-Funded Warrants at an exercise price of $2.999 per Pre-Funded Warrant. The Accompanying Warrants are exercisable any time after the date of issuance, subject to certain ownership limitations, and will expire on the fifth anniversary of the date of issuance. A holder of Accompanying Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise. The Pre-Funded Warrants have an exercise price of $0.001 per share, will be immediately exercisable subject to certain ownership limitations, and have no expiration. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise. A holder of Accompanying Warrants and Pre-Funded Warrants may increase or decrease the ownership limitation by providing at least 61 days' prior notice to us.

The June 2025 public offering of 15,000,000 Shares and 15,000,000 Accompanying Warrants raised total gross proceeds of approximately $45.0 million, and after deducting approximately $3.8 million in underwriting discounts and offering expenses, we

received net proceeds of approximately $41.2 million. The exercises in part of the Underwriters' option to purchase 1,766,666 Accompanying Warrants and 1,419,896 Shares raised gross proceeds of $4.3 million, and after deducting approximately $0.3 million in underwriting discounts, we received net proceeds of approximately $4.0 million.

Cash Flows

Operating Activities

For the years ended December 31, 2025 and 2024, net cash used in operating activities was $49.5 million and $29.8 million, respectively. The increase in net cash used in operations in 2025 as compared to 2024 was due to higher R&D expenses associated with our ORCA-OL open-label safety trial, which was initiated in May 2024, continued at full enrollment throughout the majority of 2025, and was completed in September 2025.

Financing Activities

For the years ended December 31, 2025 and 2024 net cash provided by financing activities was $51.5 million and $48.5 million, respectively. Net cash provided by financing activities for the year ended December 31, 2025 relates to proceeds received from our June 2025 public offering, warrant exercises, and the drawdown of the second tranche of the New Convertible Term Loan. Net cash provided by financing activities for the year ended December 31, 2024 relates to proceeds received from our February 2024 registered direct offering, the New Convertible Term Loan associated with the refinancing transaction in July 2024, warrant exercises, and stock sales under our employee stock purchase plan. This was partially offset by repayment of our Convertible Term Loan associated with the refinancing transaction in July 2024.

Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities was $6.1 million compared to net cash used in investing activities of $21.6 million in the year ended December 31, 2024. Net cash provided by, and used in, investing activities in 2025 and 2024 was due to transactions involving marketable securities in the normal course of business.

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 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.

Inventory Costs

Inventoriable costs, such as manufacturing costs for our product candidate, cytisinicline, are expensed as incurred as research and development expenses prior to regulatory approval. If regulatory approval of a product is obtained and the approved product is commercially launched, we will begin capitalizing manufacturing costs related to the approved product into inventory.

Research and Development Expenses

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 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 2024, the Financial Accounting Standard Board, or FASB, issued ASU2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." The standard will require additional disclosure of the nature of expenses included in the income statement in response to longstanding requests from investors for more information about an entity's expenses. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. ASU 2024-03 applies to all public business entities and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

Recent Adopted Accounting Policies

In December 2023, 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 United States. 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. We adopted this standard and applied it retrospectively. The adoption of this standard did not have a significant impact on our financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Achieve Life Sciences, Inc. and its subsidiaries (the Company) as of December 31, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America.

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

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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, 5 and 6 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, 2025, the fair value of the contingent consideration was estimated to be $1.6 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 cytisinicline'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 judgment, 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 24, 2026

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, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents *[note 3 and note 6]*	$ 20,929	$ 12,753
Marketable securities *[note 6]*	15,475	21,607
Prepaid expenses and other assets	3,292	2,107
Prepaid expenses and other assets - related parties *[note 11]*	193	—
Total current assets	**39,889**	**36,467**
Restricted cash and other assets *[note 6 and note 7]*	52	39
Right-of-use assets *[note 12]*	64	119
License agreement *[note 4 and note 5]*	751	974
Goodwill	1,034	1,034
Total assets	**$ 41,790**	**$ 38,633**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 859	$ 1,950
Accounts payable - related parties *[note 11]*	8	—
Accrued liabilities other	598	573
Accrued liabilities other - related parties *[note 11]*	6	—
Accrued clinical liabilities	368	1,077
Accrued compensation	1,921	3,027
Current contingent consideration *[note 5 and note 6]*	1,557	—
Current portion of long-term obligations *[note 12]*	61	55
Current portion of convertible debt *[note 6 and note 8]*	3,704	—
Total current liabilities	**9,082**	**6,682**
Non-current liabilities:		
Non-current portion of convertible debt *[note 6 and note 8]*	11,185	9,837
Non-current contingent consideration *[note 5 and note 6]*	—	1,149
Long-term obligations *[note 12]*	5	66
Total liabilities	**20,272**	**17,734**
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, 2025 and December 31, 2024.	—	—
Series B convertible preferred stock, $0.001 par value, 6,256 shares designated, zero issued and outstanding at December 31, 2025 and December 31, 2024.	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized, 53,233,988 and 34,685,072 issued and outstanding at December 31, 2025 and December 31, 2024, respectively.	121	103
Additional paid-in capital	281,613	226,343
Accumulated deficit	(260,226)	(205,578)
Accumulated other comprehensive income	10	31
Total stockholders' equity	**21,518**	**20,899**
Total liabilities and stockholders' equity	**$ 41,790**	**$ 38,633**
Going concern *[note 1]*		

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Loss and Comprehensive Loss

(In thousands, except per share and share amounts)

	Year Ended December 31,		
	2025	2024	2023
EXPENSES			
Research and development	$ 22,964	$ 22,817	$ 15,814
Research and development - related parties *[note 11]*	34	—	—
General and administrative	31,868	16,252	11,436
General and administrative - related parties *[note 11]*	14	—	—
Total operating expenses	54,880	39,069	27,250
OTHER INCOME (EXPENSE)			
Interest income	1,495	2,356	825
Interest expense *[note 8]*	(819)	(2,180)	(2,853)
Change in fair value of contingent consideration *[note 5 and note 6]*	(408)	(621)	(528)
Loss on extinguishment of 2023 SVB convertible term loan *[note 8]*	—	(283)	—
Other income (expense)	(36)	(30)	(9)
Total other income (expense)	232	(758)	(2,565)
Net Loss	$ (54,648)	$ (39,827)	$ (29,815)
OTHER COMPREHENSIVE INCOME (LOSS)			
Net unrealized gain (loss) on securities	(21)	27	—
Total other comprehensive income (loss)	(21)	27	—
Comprehensive loss	$ (54,669)	$ (39,800)	$ (29,815)
Basic and diluted net loss per common share *[note 10 [i]]*	$ (1.25)	$ (1.24)	$ (1.50)
Shares used in computation of basic and diluted net loss per common share *[note 10 [i]]*	43,594,652	32,071,146	19,827,534

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, 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)
Stock-based compensation expense	—	—	—	—	5,325	—	—	5,325
Shares issued on exercise of warrants	295,126	—	—	—	682	—	—	682
Shares issued - February 2024 private placement	13,086,151	13	—	—	56,063	—	—	56,076
Restricted stock unit settlements	113,125	—	—	—	—	—	—	—
Restricted stock unit settlements withheld and retired to treasury	(23,733)	—	—	—	(114)	—	—	(114)
Shares issued under employee share purchase plan	48,643	—	—	—	178	—	—	178
Other comprehensive income	—	—	—	—	—	27	—	27
Net loss	—	—	—	—	—	—	(39,827)	(39,827)
Balance, December 31, 2024	34,685,072	103	—	—	226,343	31	(205,578)	20,899
Stock-based compensation expense	—	—	—	—	8,761	—	—	8,761
Shares issued on exercise of warrants	461,500	—	—	—	1,385	—	—	1,385
Shares issued - June 2025 public offering	15,000,000	15	—	—	41,123	—	—	41,138
Shares issued - June 2025 public offering exercise of overallotment option	1,419,896	1	—	—	4,003	—	—	4,004
Restricted stock unit settlements	1,667,520	2	—	—	(2)	—	—	—
Other comprehensive income	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(54,648)	(54,648)
Balance, December 31, 2025	53,233,988	121	—	—	281,613	10	(260,226)	21,518

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Operating Activities:			
Net loss	$ (54,648)	$ (39,827)	$ (29,815)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization *[note 4]*	228	229	228
Stock-based compensation *[note 10[c], note 10[d], note 10[e] and note 10[f]]*	8,761	5,325	3,439
Shares issued as settlement with trade vendor	—	—	273
Accrued interest on SVB convertible debt *[note 8]*	—	799	1,216
Amortization of 2024 SVB convertible term loan transaction costs *[note 8]*	52	23	—
Accretion of discount on modification of debt *[note 8]*	—	365	430
Loss on extinguishment of 2023 SVB convertible term loan *[note 8]*	—	283	—
Change in fair value of contingent consideration *[note 4 and note 5]*	408	621	528
Changes in operating assets and liabilities:			
Grant receivable	—	111	(6)
Prepaid expenses and other assets	(1,204)	(765)	1,176
Prepaid expenses and other assets - related parties *[note 11]*	(193)	—	—
Accounts payable	(1,091)	1,332	(1,042)
Accounts payable - related parties *[note 11]*	8	—	—
Accrued liabilities other	25	222	(32)
Accrued liabilities other - related parties *[note 11]*	6	—	—
Accrued clinical liabilities	(709)	797	(1,449)
Accrued compensation	(1,108)	716	633
Lease obligation	—	(1)	(58)
Net cash used in operating activities	(49,465)	(29,770)	(24,479)
Financing Activities:			
Proceeds from exercise of warrants *[note 10[g]]*	1,385	682	227
Proceeds from employee stock purchase plan *[note 10[e]]*	—	178	—
Taxes paid related to net share settlement of equity awards	—	(114)	(220)
Proceeds from the November 2022 private placement, net of issuance costs *[note 10[b]]*	—	—	(30)
Proceeds from May 2023 private placement, net of issuance costs *[note 10[b]]*	—	—	15,301
Proceeds from February 2024 registered direct offering, net of issuance costs *[note 10[b]]*	—	56,076	—
Proceeds from June 2025 public offering, net of issuance costs *[note 10b]*	41,138	—	—
Proceeds from June 2025 public offering exercise of overallotment option, net of issuance costs *[note 10b]*	4,004	—	—
Repayment of 2023 SVB convertible term loan *[note 6 and note 8]*	—	(18,109)	—
Receipt of 2024 SVB convertible term loan less transaction costs *[note 6 and note 8]*	—	9,814	—
Receipt of 2024 SVB convertible term loan second tranche *[note 6 and note 8]*	5,000	—	—
Net cash provided by financing activities	51,527	48,527	15,278
Investing Activities:			
Purchase of property and equipment	(3)	—	(21)
Loss on disposal of property and equipment	(1)	—	—
Realized gain on investments	4	—	—
Purchase of investments	(24,755)	(47,887)	—
Maturities of investments	30,866	26,307	—
Net cash provided by (used in) investing activities	6,111	(21,580)	(21)
Effect of exchange rate changes on cash	3	—	(3)
Net increase (decrease) in cash, cash equivalents and restricted cash	8,176	(2,823)	(9,225)
Cash, cash equivalents and restricted cash at beginning of year	12,773	15,596	24,821
Cash, cash equivalents and restricted cash at end of year	$ 20,949	$ 12,773	$ 15,596

See accompanying notes.

Achieve Life Sciences, Inc.

Notes to Consolidated Financial Statements

(In thousands, except per share and share amounts)

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

Achieve Life Sciences, Inc. (referred to as "Achieve," "we," "us," or "our") is a late-stage clinical specialty pharmaceutical company with the sole mission to address the global nicotine dependence epidemic through the development and commercialization of cytisinicline. We were incorporated in the state of Delaware, and operate out of Bothell, Washington and Vancouver, British Columbia.

Going Concern Uncertainty

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

We have historically experienced recurring losses from operations and have incurred an accumulated deficit of $260.2 million through December 31, 2025. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $36.4 million and a positive working capital balance of $30.8 million. For the year ended December 31, 2025, we incurred a net loss of $54.6 million and net cash used in operating activities was $49.5 million.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is subject to material uncertainty and dependent on our ability to obtain additional financing. While we have historically financed our operations through equity offerings, debt financings, and government grants, the timing and amount of future financings may be impacted by macroeconomic conditions including uncertainty in the capital markets. There can be no assurance that financing from these or other sources will be available to us in the future. Without additional funds, we would be forced to delay, scale back or eliminate some of our commercialization and research and development, or R&D, activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our commercialization and development goals would be adversely affected.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Accordingly, we will need to raise substantial additional capital from the sale of our securities, debt, partnering arrangements, non-dilutive fundraising or other financing transactions in order to continue to fund our operations and finance the remaining development and commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace of our commercialization activities and the pace and results of our clinical development efforts. The uncertainty with respect to our operations and the market generally may also make it challenging to raise additional capital on favorable terms, if at all. In addition, current macroeconomic conditions have caused uncertainty in various sectors, including the capital markets. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to prepare for commercialization and develop our product candidate. We expect our expenses to substantially increase over time in connection with our ongoing activities, particularly as we prepare our commercialization activities and advance our product candidate in clinical development.

We are required to keep substantially all of our cash and cash equivalents with a single financial institution, Silicon Valley Bank, or SVB, a division of First-Citizens Bank & Trust Company, or FCB, as required by the covenants of our New Debt Agreement (Note 3 – Financial Instruments and Risk - Concentration of Cash and Cash Equivalents Risk and Note 8 – 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, 2025 and 2024.

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

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 goodwill impairment assessment, estimates and assumptions in the fair value of of the convertible debt and 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.

Marketable Securities

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

Fair value of financial instruments

The fair value of our marketable securities is based on quoted market prices and trade data for comparable securities.

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.

Leases

We account for our lease agreements in accordance with ASC Topic 842, "Leases." All leases are classified as operating leases. Right-of-use lease assets represent the right to use an underlying asset during the lease term, and the lease liabilities represent the commitment to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. When an implicit rate is not readily determinable, an incremental borrowing rate is estimated based on information available at commencement. Lease expense is recognized on a straight-line basis over the lease term. Short-term leases of twelve months or less at commencement date are expensed on a straight-line basis over the lease term.

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.

Inventory Costs

Inventoriable costs, such as manufacturing costs for our product candidate, cytisinicline, are expensed as incurred as research and development expenses prior to regulatory approval. If regulatory approval of a product is obtained and the approved product is commercially launched, we will begin capitalizing manufacturing costs related to the approved product into inventory.

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." Operating segments are identified as components of an enterprise about which separate discreet financial information is available for evaluation by our Chief Executive Officer, the chief operating decision-maker, or CODM. The CODM assesses performance based on consolidated net income that is also reported on the Consolidated Statements of Loss and Comprehensive Loss as Net Loss.

We view our operations and manage our business as one operating segment, dedicated to the development and commercialization of cytisinicline for nicotine dependence, 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 2024, the Financial Accounting Standards Board, or FASB, issued ASU 2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." The standard will require additional disclosure of the nature of expenses included in the income statement in response to longstanding requests from investors for more information about an entity's expenses. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. ASU2024-03 applies to all public business entities and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

Recent Adopted Accounting Policies

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 United States. 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. We adopted this standard and applied it retrospectively. The adoption of this standard did not have a significant impact on our financial position or results of operations.

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, 2025, approximately $0.2 million of our cash and $2.2 million of our cash equivalents (Note 6 – Fair Value Measurements) is held in a single financial institution, SVB, as required by the covenants of our New Debt Agreement (Note 8 – 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, 2025 and 2024.

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, 2025 the average days to maturity of our portfolio of cash equivalents and marketable securities was 37 days. We do not use derivative instruments to hedge against any of these financial risks.

4. 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 (in thousands):

	December 31, 2025			December 31, 2024		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (2,366)	$ 751	$ 3,117	$ (2,143)	$ 974

For the years ended December 31, 2025, 2024 and 2023, we recorded license agreement amortization expense of $0.2 million, $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, 2025:

Year Ending December 31,	
2026	223
2027	223
2028	223
2029	82
Total	**$ 751**

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 analysis of potential impairment indicators 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, 2025.

5. 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.

We communicated to Sopharma that we had concerns regarding their ability to pass an FDA pre-approval inspection and that if those concerns were not resolved, we planned to engage third-party manufacturers, and include such manufacturers in our NDA, until such time that Sopharma is able to pass an FDA inspection. In June 2025, we submitted our NDA, which included third-party manufacturers. Sopharma has alleged that our engagement of third-party manufacturers is a breach of our agreement, which we have disputed and have proposed steps to resolve.

Share Purchase Agreement

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma to acquire 75% of the outstanding shares of Extab 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. 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, 2025, the fair value of the contingent consideration was estimated to be $1.6 million (see Note 2, "Significant Accounting Policies, Sopharma Share Purchase Agreement Contingent Consideration"). We recognized losses of $0.4 million, $0.6 million and $0.5 million for the years ended December 31, 2025, 2024 and 2023, respectively.

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, 2025, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

6. 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.

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.

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

Financial Instruments

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

December 31, 2025	Level 1	Level 2	Level 3	Total
Assets				
Money market securities (cash equivalents)	$ 18,276	$ —	$ —	$ 18,276
Commercial paper (cash equivalents)	—	1,994	—	1,994
Restricted cash	20	—	—	20
US government securities	—	3,975	—	3,975
Corporate bonds	—	7,523	—	7,523
Commercial paper (marketable securities)	—	3,977	—	3,977
Total assets	**$ 18,296**	**$ 17,469**	**$ —**	**$ 35,765**
Liabilities				
Convertible debt	$ —	14,320	$ —	$ 14,320
Contingent consideration	—	—	1,557	1,557
Total liabilities	**$ —**	**$ 14,320**	**$ 1,557**	**$ 15,877**

December 31, 2024	Level 1	Level 2	Level 3	Total
Assets				
Money market securities (cash equivalents)	$ 12,135	$ —	$ —	$ 12,135
Restricted cash	20	—	—	20
US government securities	—	9,473	—	9,473
Corporate bonds	—	12,134	—	12,134
Total assets	**$ 12,155**	**$ 21,607**	**$ —**	**$ 33,762**
Liabilities				
Convertible debt	$ —	$ 9,430	$ —	$ 9,430
Contingent consideration	—	—	1,149	1,149
Total liabilities	**$ —**	**$ 9,430**	**$ 1,149**	**$ 10,579**

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.

Cash, cash equivalents and restricted cash consist of the following (in thousands):

December 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market securities	18,276	—	—	18,276
Total cash and cash equivalents	**$ 18,276**	**$ —**	**$ —**	**$ 18,276**
Money market securities (restricted cash)	20	—	—	20
Total restricted cash	**$ 20**	**$ —**	**$ —**	**$ 20**

December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market securities	12,135	—	—	12,135
Total cash and cash equivalents	**$ 12,135**	**$ —**	**$ —**	**$ 12,135**
Money market securities (restricted cash)	20	—	—	20
Total restricted cash	**$ 20**	**$ —**	**$ —**	**$ 20**

Corporate and Other Debt Corporate Bonds and Commercial Paper

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

December 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper (cash equivalents)	1,994	—	—	1,994
Total cash and cash equivalents	**$ 1,994**	**$ —**	**$ —**	**$ 1,994**
US government securities	3,973	2	—	3,975
Corporate bonds	7,520	3	—	7,523
Commercial paper	3,976	1	—	3,977
Total marketable securities	**$ 15,469**	**$ 6**	**$ —**	**$ 15,475**

December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	$ 9,461	$ —	$ 12	$ 9,473
Corporate bonds	12,119	—	15	12,134
Total marketable securities	**$ 21,580**	**$ —**	**$ 27**	**$ 21,607**

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, 2025 and December 31, 2024 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, 2025			December 31, 2024		
	Principal Amount	Carrying Value	Fair Value	Principal Amount	Carrying Value	Fair Value
2024 SVB Convertible Debt	$ 15,000	$ 14,889	$ 14,320	$ 10,000	$ 9,837	$ 9,430

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 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 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, 2025 the risk adjusted discount rate was 30.8% and the probability of success was 90.6%. 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.

The following table presents the changes in fair value of our total Level 3 financial liabilities for the year ended December 31, 2025 (in thousands):

(in thousands)	Opening Balance at December 31, 2024	Change in Fair Value	Balance at December 31, 2025
Contingent consideration	$ 1,149	$ 408	$ 1,557

7. PROPERTY AND EQUIPMENT

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

	Cost	Accumulated Depreciation	Net Book Value
December 31, 2025			
Computer equipment	$ 114	$ 111	$ 3
Furniture and fixtures	28	28	—
Leasehold improvements	25	25	—
Computer software	77	77	—
Equipment under capital lease	12	12	—
Total property and equipment	$ 256	$ 253	$ 3
December 31, 2024			
Computer equipment	$ 114	$ 108	$ 6
Furniture and fixtures	28	28	—
Leasehold improvements	25	25	—
Computer software	77	75	2
Equipment under capital lease	12	12	—
Total property and equipment	$ 256	$ 248	$ 8

8. CONVERTIBLE DEBT

On July 25, 2024, we entered into a contingent convertible debt agreement, or New Debt Agreement, with Silicon Valley Bank, or SVB, a division of First-Citizens Bank & Trust Company, or FCB, in its capacity as administrative agent and collateral agent, and FCB, as a lender, or Lender, pursuant to which the Lender provided term loans having an aggregate original principal amount of $10.0 million, with additional term loans of up to $10.0 million available upon the occurrence of certain events as provided for in the New Debt Agreement and further described below, or New Convertible Term Loan. Our obligations under the New Debt Agreement are secured by substantially all of our assets, other than intellectual property.

The New Convertible Term Loan matures on June 1, 2028. The first tranche of the New Convertible Term Loan, which was advanced on July 25, 2024, has an aggregate original principal amount of $10.0 million. The Lender made available to us, upon our request: (a) prior to October 31, 2025, a second tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million in the event that we received written notice that the FDA had accepted for filing our NDA with respect to cytisinicline for a smoking cessation indication, or the Additional Term Loan Event I, and (b) on or prior to December 31, 2025, a third tranche of the New Convertible Term Loan having an aggregate principal amount of $5.0 million, subject to the Lender's sole discretion.

In October 2025, pursuant to the New Debt Agreement and following the occurrence of the Additional Term Loan Event I (as described therein), we drew down on the second tranche of the New Convertible Term Loan for an additional $5.0 million. We did not draw down on the third tranche of the New Convertible Term Loan and it expired and became unavailable on December 31, 2025. Interest is calculated on the outstanding principal amount of the New Convertible Term Loan at a floating rate per annum equal to the greater of (i) 7.0% and (ii) the prime rate minus 1.0%, which interest shall be payable in cash monthly in arrears and shall be payable on the earlier to occur of (x) the first day of the first month following any extension of credit by the Lender for our credit, (y) the date of any prepayment pursuant to the New Debt Agreement, or (z) the maturity date. The New Convertible Term Loan will be "interest-only" until June 30, 2026.

Subject to certain terms and conditions, the conversion feature grants the Lender or, pursuant to an assignment, any designee thereof, or Conversion Right Holders, the right to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to $7.00, subject to customary adjustment provisions. The Conversion Right Holders have the further right to convert part or all of the outstanding principal amount of the second tranche of the New Convertible Term Loan, plus accrued and unpaid interest, into shares of our common stock at a conversion price equal to the greater of (i) $4.854, subject to customary adjustment provisions, and (ii) the lower of (a) 150% of the average of the closing sale price of our common stock during the 10 trading days preceding the effective date of such tranche and (b) 150% of the closing sale price of our common stock on the trading day immediately preceding the effective date of such tranche.

The conversion rights may be exercised at each Conversion Right Holder's option any time prior to repayment of the New Convertible Term Loan; provided, however, that the Conversion Right Holders will not be permitted to convert part or all of the outstanding aggregate original principal amount of the New Convertible Term Loan without the agreement of the relevant Conversion Right Holder and us if the sum of the amount of debt to be converted; and the aggregate amount of debt previously converted pursuant to any such voluntary conversion, divided by the aggregate of all debt that is then outstanding or that has been repaid other than by conversion exceeds 50%.

Additionally, the outstanding principal of the New Convertible Term Loan, plus accrued and unpaid interest, will automatically be converted into shares of our common stock at the applicable conversion price on such date if any, when the closing price per share of our common stock has been equal to or greater than (a) in the case of the outstanding aggregate original principal amount of the New Convertible Term Loan, plus accrued and unpaid interest, $24.00 or, (b) in the case of the outstanding principal amount of the second tranche of the New Convertible Term Loan, plus accrued and unpaid interest, three times the applicable conversion price, in each case for the thirty consecutive trading days prior to such date, and the Liquidity Conditions (as defined in the New Debt Agreement) have been satisfied.

The New Convertible Term Loan may be repaid at our election and upon notice to the Agent (as defined in the New Debt Agreement) by paying the Lender an amount equal to (i) a prepayment fee equal to (a) 3.0% of the aggregate outstanding principal balance if such prepayment occurs on or prior to the first anniversary of the New Convertible Term Loan, (b) 2.0% of the aggregate outstanding principal balance if such prepayment occurs after the first anniversary, but on or prior to the second anniversary, of the New Convertible Term Loan or (c) 1.0% of the aggregate outstanding principal balance if such prepayment occurs after the second anniversary of the New Convertible Term Loan and before the maturity date; (ii) 4.0% of the original aggregate principal amount of the New Convertible Term Loan and (iii) all other sums due and payable under the New Convertible Term Loan.

The New 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 New Debt Agreement also includes customary representations and warranties, events of default and termination provisions. The Lender may not engage in any short sales of, or other hedging transactions in, our common stock while any amounts are outstanding under the New Debt Agreement. As of December 31, 2025, we are in compliance with all covenants under the New Debt Agreement.

In connection with the New Debt Agreement, we entered into a Registration Rights Agreement, or RRA, with the Lender, pursuant to which we registered for resale shares of our common stock issuable to the Conversion Right Holders upon the conversion of outstanding debt under the New Debt Agreement. Our obligations under the RRA will terminate with respect to a holder of applicable registrable securities if, as of the date we would be required to provide written notice of such registration, (x) the aggregate number of registrable securities then issued and issuable to such holder and to such holder's affiliates, together with all other shares then held beneficially and/or of record by such holder and its affiliates, does not exceed 7.0% of our then-total shares issued and outstanding (calculated including all such registrable securities and other shares), or (y) we and such holder mutually reasonably agree that all registrable securities then issued and issuable to such holder and its affiliates may then be sold by such holder without the requirement to be in compliance with Rule 144 promulgated under the Securities Act, or Rule 144, and otherwise without restriction or limitation pursuant to Rule 144.

Under ASU 2020-06 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 refinancing under the New Debt Agreement was recognized as an extinguishment of debt under ASC 470-50, and the difference between the reacquisition price and carrying value was recognized on the Consolidated Statement of Loss as a loss on extinguishment of debt. Associated third-party issuance costs have been recognized against the single unit of debt and will be amortized into interest expense over the term of the loan.

As of December 31, 2025, the New Convertible Term Loan balance was comprised of the following (in thousands):

	Year Ended December 31,	
	2025	2024
New Convertible Term Loan Information		
Principal	$ 15,000	$ 10,000
Transaction costs	(186)	(186)
Amortization of transaction costs	75	23
	14,889	9,837

9. INCOME TAX

[a] We are a Delaware incorporated company subject to U.S. Federal statutory rates for December 31, 2025, 2024 and 2023 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):

	2025	2024	2023
U.S.	$ (54,192)	$ (39,532)	$ (28,982)
Foreign	(456)	(295)	(833)
Income (loss) before income taxes	$ (54,648)	$ (39,827)	$ (29,815)

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

	2025		2024		2023	
Income tax recovery at U.S. federal statutory income tax rate	$ (11,476)	21.0%	$ (8,364)	21.0%	$ (6,261)	21.0%
Domestic state & local income tax, net of federal income tax effect	—	0.0%	—	0.0%	—	0.0%
Foreign tax effects						
Canada						
Impact of tax attribute expirations	2,312	-4.2%	—	0.0%	—	0.0%
Changes in valuation allowance	(2,278)	4.2%	31	-0.1%	40	-0.1%
Other	61	-0.1%	(6)	0.0%	(9)	0.0%
Other foreign jurisdictions	1	0.0%	37	-0.1%	144	-0.5%
Enactment of new tax laws	—	0.0%	—	0.0%	—	0.0%
Effect of cross-border laws	—	0.0%	—	0.0%	—	0.0%
Tax credits						
Research and development tax credits	(839)	1.5%	(1,084)	2.7%	(1,643)	5.5%
Other	—	0.0%	—	0.0%	—	0.0%
Changes in valuation allowance	10,860	-19.9%	8,527	-21.4%	7,243	-24.3%
Non-taxable or non-deductible items						
Stock Based Compensation	1,077	-2.0%	610	-1.5%	360	-1.2%
Other	265	-0.5%	293	-0.7%	116	-0.4%
Changes in unrecognized tax benefits	—	0.0%	—	0.0%	—	0.0%
Other	17	0.0%	(44)	0.1%	10	0.0%
Income tax expense/(recovery)	$ —	0.0%	$ —	0.0%	$ —	0.0%

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

	2025	2024
Deferred tax assets		
Net operating loss carryforwards	$ 64,863	$ 54,553
Research and development credits	12,416	11,800
Stock based compensation	1,594	1,535
Capitalized R&D expenses	10,572	12,840
Other, net	1,263	1,432
Total deferred tax assets	90,708	82,160
Valuation allowance	(90,425)	(81,830)
Net deferred tax assets	283	330
Deferred tax liabilities		
Other	(283)	(330)
Total deferred tax liabilities	(283)	(330)
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 $90.4 million to reduce the DTAs to zero as of December 31, 2025. The valuation allowance increased by approximately $8.6 million during the year ended December 31, 2025. 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 $175.3 million ($116.8 million—2024) as of December 31, 2025, some of which will begin to expire in 2029. Approximately $165.2 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 $6.0 million ($5.1 million—2024) as of December 31, 2025, 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, or IRC, Section 382. Sections 382 and 383 of the IRC limit the utilization of tax attribute carryforwards that arise prior to certain cumulative changes in a corporation's ownership. Our attribute carryforwards may be limited due to a change of control in ownership as defined by Section 382. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate. 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, 2025, we have Canadian non-capital loss carryforwards of $100.0 million ($107.3 million—2024) and research tax credits of $1.9 million ($2.7 million—2024), both of which will begin to expire in 2026. 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 $4.2 million (2024—$4.2 million) will carry forward indefinitely. As of December 31, 2025 and 2024, there are no tax penalties or accrued interest recorded in the financial statements.

The components of cash income taxes paid net of refunds are as follows (in thousands):

	Year ended December 31,		
	2025	2024	2023
Federal	$ —	$ —	$ —
State and local	—	—	—
Foreign	—	—	—
Total	$ —	$ —	$ —

[c] A reconciliation of the unrecognized tax benefits of uncertain tax positions for the year ended December 31, 2025 is as follows (in thousands):

	Year ended December 31,		
	2025	2024	2023
Gross unrecognized tax benefits at January 1	$ 761	$ 761	$ 761
Additions (reductions) from tax positions taken in prior years	—	—	—
Additions (reductions) from tax positions taken in the current year	—	—	—
Tax settlements	—	—	—
Gross unrecognized tax benefits at December 31	$ 761	$ 761	$ 761

As of December 31, 2025, unrecognized benefits of approximately $0.8 million, if recognized, would affect our effective tax rate, and would reduce our deferred tax assets. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits will have no impact on our effective tax rate. We do not anticipate that there will be a substantial change in unrecognized tax benefits within the next 12 months.

Our accounting policy is to treat interest and penalties relating to unrecognized tax benefits as a component of income taxes. As of December 31, 2025 and December 31, 2024 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	2021 to 2025
United Kingdom	2019 to 2025
US	2022 to 2025

10. 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 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.

February 2024 Registered Direct Offering and Concurrent Private Placement

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 28, 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 are immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof, and expired in October 2025 on the date 30 days after our public disclosure of the acceptance of an NDA filing for cytisinicline by the FDA in a Day 74 Letter or equivalent correspondence. The shares of common stock issuable upon exercise of the warrants (or pre-funded warrants, as applicable) were subsequently registered pursuant to our registration statement on Form S-3, which was declared effective on May 6, 2024.

The registered direct offering raised total gross proceeds of approximately $60.0 million, and after deducting approximately $3.9 million in placement agent fees and offering expenses, we received net proceeds of approximately $56.1 million.

Jefferies Open Market Sale Agreement

On September 27, 2024, we entered into an Open Market Sale Agreement, or Sale Agreement, with Jefferies LLC, or Jefferies, as sales agent, to establish an at-the-market offering program through which we may sell shares of our common stock with an aggregate offering price of up to $50.0 million. On November 6, 2025, the Sale Agreement with Jeffries was terminated and no further sales of our common stock were made pursuant to the Sale Agreement.

June 2025 Public Offering

On June 26, 2025, we entered into an underwriting agreement, or Underwriting Agreement, with Citizens JMP Securities, LLC and Raymond James & Associates, Inc., or the Underwriters, as representatives of the underwriters, pursuant to which we agreed to issue and sell to the Underwriters 15,000,000 shares of our common stock, or the Shares, and accompanying common warrants, or Accompanying Warrants, to purchase up to 15,000,000 shares of common stock, or Warrant Shares, or pre-funded warrants to purchase shares of our common stock in lieu thereof, or Pre-Funded Warrants.

The Shares and Accompanying Warrants were sold collectively at the public offering price of $3.00 per Share and Accompanying Warrant, less underwriting discounts and commissions. Pursuant to the Underwriting Agreement, we also granted the Underwriters a 30-day option to purchase up to an additional 2,250,000 Shares and/or up to an additional 2,250,000 Accompanying Warrants at the same public offering price per Share and Accompanying Warrant, less underwriting discounts and commissions. On June 28, 2025, the Underwriters exercised their option in part to purchase an additional 1,766,666 Accompanying Warrants. On July 25, 2025, the Underwriters exercised their option in part to purchase an additional 1,419,896 Shares.

Each Accompanying Warrant is exercisable, at the purchaser’s election, for either Warrant Shares at an exercise price of $3.00 per share or for Pre-Funded Warrants at an exercise price of $2.999 per Pre-Funded Warrant. The Accompanying Warrants are exercisable any time after the date of issuance, subject to certain ownership limitations, and will expire on the fifth anniversary of the date of issuance. A holder of Accompanying Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise. The Pre-Funded Warrants have an exercise price of $0.001 per share, will be immediately exercisable subject to certain ownership limitations, and have no expiration. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise. A holder of Accompanying Warrants and Pre-Funded Warrants may increase or decrease the ownership limitation by providing at least 61 days' prior notice to us.

The June 2025 public offering of 15,000,000 Shares and 15,000,000 Accompanying Warrants raised total gross proceeds of approximately $45.0 million, and after deducting approximately $3.8 million in underwriting discounts and offering expenses, we received net proceeds of approximately $41.2 million. The exercises in part of the Underwriters’ option to purchase 1,766,666 Accompanying Warrants and 1,419,896 Shares raised gross proceeds of $4.3 million, and after deducting approximately $0.3 million in underwriting discounts, we received net proceeds of approximately $4.0 million.

Equity Award Issuances and Settlements

During the year ended December 31, 2025, we did not issue any shares of common stock to satisfy stock option exercises and we issued 1,667,520 shares of common stock to satisfy restricted stock unit settlements. During the year ended December 31, 2024, we did not issue any shares of common to satisfy stock option exercises and we issued 113,125 shares of common stock to satisfy restricted stock unit settlements.

[c] Equity Awards

2024 Equity Inducement Plan

As of December 31, 2025, we had reserved, pursuant to the 2024 Equity Inducement Plan, 1,082,000 shares of common stock for issuance upon exercise of stock options and settlement of restricted stock units by employees, of which 637,000 shares were reserved for options currently outstanding and 445,000 shares were available for future equity grants.

Under the 2024 Equity Inducement Plan, we may grant options to purchase shares of our common stock or restricted stock units as a material inducement to new employees for entering into employment with us. 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. The expiration date for each option is set by our Board with a maximum

expiration date of ten years from the date of grant. In addition, the 2024 Equity Inducement Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control.

2023 Non-Employee Director Equity Incentive Plan

As of December 31, 2025, 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 290,250 shares were reserved for options currently outstanding and 9,750 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 expiration date for each option is set by our Board with a maximum expiration 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, 2025, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 2,902,149 shares of our common stock for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 1,667,405 were reserved for options currently outstanding, 1,084,330 for restricted stock units currently outstanding, and 150,414 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 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 expiration date for each option is set by our Board with a maximum expiration 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 grants are issued pursuant to a stock option agreement on terms substantially similar to the 2018 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. The expiration date for each option is set by our Board with a maximum expiration date of ten years from the date of grant. For the year ended December 31, 2025, we did not grant stock options to new employees under Nasdaq Listing Rule 5635(c)(4). As of December 31, 2025, 125,000 stock options granted as new employee inducement grants were outstanding.

2017 Equity Incentive Plan

As of December 31, 2025, we had reserved, pursuant to the 2017 Equity Incentive Plan, or the 2017 Plan, 10,536 shares of our common stock 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 expiration date for each option was set by our Board with a maximum expiration 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, 2025, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 20 shares of our common stock 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 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 expiration date for each option is set by our Board with a maximum expiration 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 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:

	2025	2024
Risk-free interest rates	3.93%	4.00%
Expected dividend yield	0%	0%
Expected life	5.89 years	5.74 years
Expected volatility	79.72%	87.40%
Forfeiture rate	0%	0%

The weighted average fair value of stock options granted during the year ended December 31, 2025 was $3.81.

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,		
	2025	2024	2023
Research and development	$ 2,515	$ 1,736	$ 1,122
General and administrative	6,246	3,589	2,317
Total stock-based compensation	$ 8,761	$ 5,325	$ 3,439

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, 2025	**2,139,414**	$ 9.18
Granted	929,500	3.81
Expired	(322,203)	11.64
Forfeited	(16,500)	6.46
Balance, December 31, 2025	**2,730,211**	**$ 7.08**

The following table summarizes information about stock options outstanding at December 31, 2025 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)
$3.10 - $3.10	321,000	$ 3.10	9.75
$3.11 - $4.18	313,500	3.62	9.27
$4.19 - $4.54	236,000	4.52	8.75
$4.55 - $4.67	388,500	4.55	8.06
$4.68 - $4.84	295,000	4.78	9.92
$4.85 - $4.99	307,250	4.90	7.07
$5.00 - $6.15	219,750	5.92	7.25
$6.16 - $8.43	269,450	7.84	6.01
$8.44 - $12.60	165,280	10.66	4.59
$12.61 - $2,200.00	214,481	29.22	4.62
	2,730,211	**$ 7.08**	**7.80**

(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)
$3.11 - $4.18	37,001	$ 3.30	9.04
$4.19 - $4.54	82,749	4.52	8.57
$4.55 - $4.67	305,082	4.55	8.06
$4.85 - $4.99	295,070	4.90	7.07
$5.00 - $6.15	206,064	5.92	7.25
$6.16 - $8.43	267,888	7.85	6.01
$8.44 - $12.60	165,280	10.66	4.59
$12.61 - $2,200.00	214,481	29.22	4.62
	1,573,615	**$ 9.33**	**6.63**

As of December 31, 2025, 2024 and 2023, the total unrecognized compensation expense related to stock options granted was $2.9 million, $2.4 million and $3.4 million, respectively, each of which is expected to be recognized as expense over a period of approximately 2.84 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,

2025, 2024 and 2023. At December 31, 2025, the aggregate intrinsic value of the outstanding options was $1.4 million and the aggregate intrinsic value of the exercisable options was $0.2 million.

[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, 2025, 2024 and 2023, $6.8 million, $2.0 million and $0.9 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, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, January 1, 2025	**1,283,750**	**$ 4.65**
Granted	1,487,400	3.20
Released	(1,667,520)	3.95
Cancelled/Forfeited	(19,300)	3.86
Balance, December 31, 2025	**1,084,330**	**$ 3.76**

As of December 31, 2025, we had approximately $2.1 million in total unrecognized compensation expense related to our restricted stock unit awards that is to be recognized over a weighted-average period of approximately 0.50 years.

[e] Employee Stock Purchase Plan

Our Board 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 number of shares available for future purchases under the ESPP is 854,477 shares. All shares purchased under the ESPP are new share issuances. For the years ended December 31, 2025 and 2024 we recorded a compensation expense of $14,000 and $0.2 million, respectively, related to the ESPP offering period. For the year ended December 31, 2023, no compensation expense was recognized related to our ESPP as we did not have an active offering period.

[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, 2025:

	Total Outstanding and Exercisable		Exercise price per Share	Expiration Date
(1) Pre-Funded Warrants issued in August 2020 financing	142,857	$	0.0010	*
(2) Warrants issued in November 2022 financing	4,093,141	$	4.5000	November 2029
(3) Warrants issued in June 2025 financing	16,305,166	$	3.0000	June 2030

* 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 in a private placement in November 2022);
- 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;
- in the case of certain warrants, 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; and
- with respect to the 2024 Warrants, and the warrants issued in the June 2025 financing, or the 2025 Warrants, and together with the 2024 Warrants, the Warrants, in the event we consummate a "fundamental transaction," as described in the Warrants and generally including a merger or consolidation with or into another entity or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, we are not the surviving entity and in which our stockholders immediately prior to the merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation (excluding any merger effected solely to change the Company's name), or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or another entity acquires 50% or more of our outstanding shares of common stock, then following such event, the holders of the Warrants will be entitled to receive upon exercise of such Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Warrants. Additionally, as more fully described in the Warrants, in the event of certain fundamental transactions, the holders of the Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Warrants on the date of consummation of such transaction.

For the year ended December 31, 2025, 2025 Warrants to purchase 461,500 shares, issued in the June 2025 financing, were exercised at a per unit price of $3.00, for proceeds of $1.4 million. For the year ended December 31, 2024, warrants to purchase 295,126 shares, issued in the December 2019 financing, were exercised at a per unit price of $2.31, for proceeds of $0.7 million. As of December 31, 2025, all of our outstanding warrants were 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,		
	2025	2024	2023
Numerator			
Net loss	$ (54,648)	$ (39,827)	$ (29,815)
Denominator			
Weighted average number of common shares outstanding	43,594,652	32,071,146	19,827,534
Basic and diluted net loss per common share	$ (1.25)	$ (1.24)	$ (1.50)

As of December 31, 2025, a total of 24,355,705 million shares, consisting of warrants to purchase 20,541,164 shares, options exercisable for 2,730,211 shares and 1,084,330 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, 2025, the outstanding New Convertible Term Loan was not included in the calculation of diluted per share amounts as its effect would have been anti-dilutive.

11. RELATED PARTY TRANSACTIONS

From September 25, 2025 to December 22, 2025, we entered into three development agreements, or the Adare Agreements, with Adare Pharma Solutions, or Adare, to perform analytical and drug product development for cytisinicline. Thomas Sellig is the current Chief Executive Officer of Adare. Mr. Sellig is also a member of our Board, chairs the Compensation Committee of the Board and is a member of the Audit Committee of the Board.

We expect to incur approximately $3.2 million in expenses over the term of the Adare Agreements. Adare will invoice us for work completed under the agreements based on industry standard payment terms. For the year ended December 31, 2025, we incurred expenses of $34,000 related to the Adare Agreements. As of December 31, 2025, we recorded a prepayment of $0.2 million on our balance sheet related to the Adare Agreements.

On November 10, 2025 we entered into a consulting agreement with Kristen Slaoui to provide strategic business development and transaction advisory support services. Dr. Slaoui is a member of our Board, the Compensation Committee of the Board and the Nominating and Corporate Governance Committee of the Board. We incurred consulting fees from Dr. Slaoui of $13,750 for the year ended December 31, 2025. As of December 31, 2025, we recorded amounts payable to Dr. Slaoui of $8,250 in accounts payable and $5,500 in accrued liabilities on our balance sheet.

12. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of December 31, 2025 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Vancouver office operating lease	$ 71	$ 66	$ 5	$ —	$ —
Total	$ 71	$ 66	$ 5	$ —	$ —

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. On December 9, 2024, we extended the lease for a further two-year term, which commenced on February 1, 2025. 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):

2026	66
2027	5
Total	**$ 71**

Consolidated rent and operating expense relating to the Vancouver, Canada office for years ended December 31, 2025, 2024 and 2023 was $0.1 million, $0.1 million and $0.1 million, respectively.

Other information related to leases was as follows:

	Year Ended December 31,	
	2025	2024
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 114	$ 59
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	—	—
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, 2025.

We have certain agreements with certain organizations with which we do business that contain indemnification provisions pursuant to which we typically agree 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.

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, 2025.

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, 2025 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, 2025, 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, 2025.

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

Insider Trading Arrangements

During the three months ended December 31, 2025, none of our directors or officers, as defined in Rule 16a-1(f), informed us of the adoption, modification or termination of a "Rule 10b5-1 trading agreement" or "non-Rule 10b5-1 trading agreement," as those terms are defined in Regulations S-K, Item 408.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain information required by this Item is set forth in our 2026 Proxy Statement to be filed with the SEC within 120 days of December 31, 2025, and is incorporated by reference into this Annual Report on Form 10-K.

Insider Trading Policy

We have adopted an Insider Trading Policy that governs the purchase, sale and/or other dispositions of our securities by directors, officers and employees. Our Insider Trading Policy also provides that we will not transact in any of our own securities unless in compliance with U.S. securities laws. We believe that our Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in our 2026 Proxy Statement to be filed with the SEC within 120 days of December 31, 2025, 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, 2025:

	(a)		(b)		(c)	
Plan category	Number of securities to be issued upon exercise of outstanding options, restricted stock units, warrants and rights		Weighted-average exercise price of outstanding options, warrants and rights		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	3,052,541	(1)	$ 8.04	(1)	160,164	(1)
Equity compensation plans not approved by security holders[(2)]	762,000		$ 4.58		445,000	
Total	3,814,541		$ 7.08		605,164	

(1) As of December 31, 2025, 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 under our 2024 Equity Inducement Plan as inducements 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 2026 Proxy Statement to be filed with the SEC within 120 days of December 31, 2025, 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 2026 Proxy Statement to be filed with the SEC within 120 days of December 31, 2025, 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 2026 Proxy Statement to be filed with the SEC within 120 days of December 31, 2025, 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 Pre-Funded Warrant (August 2020)	8-K	033-80623	4.1	August 4, 2020	
4.5	Form of Underwriter's Warrant	S-1	333-250074	4.11	November 30, 2020	
4.6	Form of Common Stock Purchase Warrant (November 2022)	8-K	033-80623	4.1	November 18, 2022	
4.7	Form of Registration Rights Agreement	8-K	033-80623	10.2	November 18, 2022	
4.8	Registration Rights Agreement, dated July 25, 2024, between Achieve Life Sciences, Inc., and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company	8-K	033-80623	10.2	July 29, 2024	
4.9	Form of Warrant to Purchase Common Stock or Pre-Funded Warrants	8-K	033-80623	4.1	June 27, 2025	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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	2024 Equity Inducement Plan and forms of award agreements thereunder	S-8	333-283630	99.1	December 5, 2024	
10.11	Form of Indemnification Agreement for Officers and Directors of the Company	10-K	033-80623	10.10	March 28, 2024	
10.12	Employment Agreement between the Company and Richard Stewart, executed May 22, 2018 ††	8-K	033-80623	10.1	May 23, 2018	
10.13	Executive Employment Agreement, dated August 26, 2024, between Achieve Life Sciences, Inc. and Thomas B. King	10-Q	033-80623	10.4	November 7, 2024	
10.14	Amended and Restated Employment Agreement, dated October 16, 2024, between Achieve Life Sciences, Inc. and Jaime Xinos					X
10.15	Executive Employment Agreement, dated May 9, 2025, by and between Achieve Life Sciences, Inc. and Richard Stewart	10-Q	033-80623	10.1	August 7, 2025	
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	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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*	10-K	033-80623	10.21	March 28, 2024	
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	Contingent Convertible Debt Agreement, dated July 25, 2024, between Achieve Life Sciences, Inc., and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company	8-K	033-80623	10.1	July 29, 2024	
10.27	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	
10.28	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	

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.29	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	
10.30	Office Lease by and between Regus Management Group, LLC and Achieve Life Sciences, Inc., commencing March 1, 2024	10-K	033-80623	10.32	March 28, 2024	
10.31	Lease Extension Agreement by and between Regus Management Group, LLC and Achieve Life Sciences, Inc., commencing March 1, 2024	10-K	033-80623	10.36	March 11, 2025	
10.32	Consulting Agreement, dated November 10, 2025, by and between Achieve Life Sciences, Inc. and Kristen Slaoui					X
19.1	Insider Trading Policy	10-K	033-80623	19.1	March 11, 2025	
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) pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer (Principal 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) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**					X
32.2	Certification of Chief Financial Officer (Principal 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	10-K	033-80623	97.0	March 28, 2024	

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 24, 2026

By: /s/ MARK OKI
Mark Oki
Chief Financial Officer (Principal Financial Officer)

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark Oki 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/ RICHARD STEWART Richard Stewart	President, Chief Executive Officer and Director (Principal Executive Officer)	Date: March 24, 2026
By: /s/ MARK OKI Mark Oki	Chief Financial Officer (Principal Financial Officer)	Date: March 24, 2026
By: /s/ JERRY WAN Jerry Wan	Vice President, Finance (Principal Accounting Officer)	Date: March 24, 2026
By: /s/ THOMAS B. KING Thomas B. King	Chairman of the Board of Directors	Date: March 24, 2026
By: /s/ BRIDGET MARTELL Bridget Martell	Director	Date: March 24, 2026
By: /s/ STUART DUTY Stuart Duty	Director	Date: March 24, 2026
By: /s/ THOMAS SELLIG Thomas Sellig	Director	Date: March 24, 2026
By: /s/ KRISTEN SLAOUI Kristen Slaoui	Director	Date: March 24, 2026
By: /s/ NANCY R. PHELAN Nancy R. Phelan	Director	Date: March 24, 2026