UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission File Number: 001-40493

ATAI Life Sciences N.V.

(Exact name of registrant as specified in its charter)

The Netherlands **(State or other jurisdiction of incorporation or organization)**	**Not Applicable** **(I.R.S. Employer Identification No.)**
ATAI Life Sciences N.V. **Wallstraße 16, 10179** **Berlin, Germany** **(Address of principal executive offices)**	**Not Applicable** **(Zip Code)**

+49 89 2153 9035
(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 each exchange on which registered
Common shares, par value €0.10 per share	**ATAI**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒ Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 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 Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $172.9 million. Solely for purposes of this disclosure, common shares held by executive officers, directors and certain shareholders of the Registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 11, 2025, the Registrant had 198,306,455 common shares, par value €0.10 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement relating to its 2025 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission (the "SEC") within 120 days after the end of the fiscal year ended December 31, 2024, are incorporated herein by reference in Part III where indicated.

ATAI Life Sciences N.V.

FORM 10-K

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (the "Form 10-K") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this Form 10-K other than statements of historical fact should be considered forward-looking statements, including without limitation statements regarding our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue; the timing of and our ability to obtain and maintain regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, such as the acquisition of IntelGenx Corp., partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents and short-term investments to fund our operations; available funding under the 2022 Term Loan Facility; and the plans and objectives of management for future operations and capital expenditures. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are neither promises nor guarantees, and are subject to a number of important factors that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation: the risks, uncertainties, and assumptions described under "Summary Risk Factors" below, "Risk Factors" in Item 1A of Part I, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II and elsewhere in this Form 10-K.

Any forward-looking statements made herein speak only as of the date of this Form 10-K, and you should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, performance, or achievements reflected in the forward-looking statements will be achieved or will occur. Except as required by applicable law, we undertake no obligation to update any of these forward-looking statements for any reason after the date of this Form 10-K or to conform these statements to actual results or revised expectations. Additionally, certain information we may disclose (either herein or elsewhere) is informed by the expectations of various stakeholders or third-party frameworks and, as such, may not necessarily be material for purposes of our filings under U.S. federal securities laws, even if we use "material" or similar language in discussing such matters.

GENERAL

Unless the context otherwise requires, all references in this Form 10-K to "we," "us," "our," "atai" or the "Company" refer to ATAI Life Sciences N.V. and its consolidated subsidiaries. References to "Form 10-K" and "Annual Report" herein refer to this Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

We were incorporated pursuant to the laws of the Netherlands as Adripa Holding B.V. on September 10, 2020 to become a holding company for ATAI Life Sciences AG and on January 11, 2021, our name was changed to ATAI Life Sciences B.V. Prior to our initial public offering ("IPO") on June 22, 2021, we converted the legal form of ATAI Life Sciences B.V. into a public company with limited liability and our name into ATAI Life Sciences N.V.

We may announce material business and financial information to our investors using our investor relations website at https://ir.atai.com. We therefore encourage investors and others interested in atai to review the information that we make available on our website, in addition to following our filings with the U.S. Securities and Exchange Commission ("SEC"), webcasts, press releases and conference calls. Information contained on our website is not part of this Annual Report on Form 10-K.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those summarized below. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the headings "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common shares could decline. The principal risks and uncertainties affecting our business include the following:

- We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never be profitable;
- Our limited operating history may make it difficult for you to evaluate the success of our business and to assess our future viability;
- If we are unable to obtain funding when needed and on acceptable terms, we could be forced to delay, limit or discontinue our product candidate development efforts;
- Raising additional capital, such as through future sales and issuances of our common shares or rights to purchase common shares, including pursuant to our equity incentive plans, may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to current product candidates or to any future product candidates on unfavorable terms;
- As a result of covenants related to our Loan Agreement with Hercules, our operating activities may be restricted and we may be required to repay the outstanding indebtedness in the event of a breach by us, or an event of default thereunder, which could have a materially adverse effect on our business;
- Our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes. We cannot give any assurance that any of our product candidates will be successfully developed and/or receive regulatory approval, which is necessary before they can be commercialized;
- Because we have multiple programs and product candidates in our development pipeline, in addition to our continued business development activities, we may, and have in the past decided to, expend our limited resources and allocation of capital to pursue a particular product candidate over other product candidates that may ultimately have been more profitable or for which there may have been a greater likelihood of success, which may adversely affect our future revenues;
- We may not achieve our publicly announced milestones according to schedule, or at all;
- We currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials, and we expect this to continue upon approval, if any, of our current or future product candidates. If third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed;
- Research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others, which may reduce the likelihood our product candidates are ultimately approved and therefore may have a material adverse effect on our business and operating results;
- The production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions and therefore we may not be successful in commercializing our product candidates in such jurisdictions, which will adversely affect our business, financial condition and results of operations;
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before we do or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition;
- We rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing;
- If we are unable to obtain and maintain sufficient intellectual property protection for our existing product candidates or any other product candidates that we may identify, or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical

to ours, and our ability to successfully commercialize our existing product candidates and any other product candidates that we may pursue may be impaired;

- Third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts;
- Our business is subject to global financial and economic conditions and geopolitical events, including overall market volatility in the global financial markets, as well as political, trade and regulatory developments;
- Our business is subject to economic, political, regulatory and other risks associated with international operations;
- Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel;
- A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business, including our preclinical studies, clinical trials, trial sites, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results; and
- If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes. Founded in 2018, atai emerged from the urgent need for better mental health solutions for patients who are under-served by current treatment options. We are advancing a pipeline of product candidates designed to address the complex nature of mental health disorders. We believe that these investigational compounds have the potential to become rapid-acting, durable, and commercially scalable therapies for mental health patients in need of new treatment options.

Mental health disorders are highly prevalent and estimated to affect more than one billion people globally. The economic burden of these disorders is substantial and growing rapidly. Between 2009 and 2019, spending on mental health care in the United States increased by more than 50%, reaching $225 billion, and a Lancet Commission report estimates that the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors (“SSRIs”) and serotonin-norepinephrine reuptake inhibitors (“SNRIs”) are well established and effective for certain patients, approximately 65% of patients do not achieve remission of their symptoms after up to four antidepressant treatment trials, translating to a significant unmet medical need.

Our Approach

Our research is focused on developing rapid-acting, robust, and durable mental health treatments that can deliver large-scale patient impact. We are committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change. We pursue this in two ways: we develop novel product candidates in-house and we make strategic investments in companies developing promising product candidates.

Our Core Psychedelic Programs

We have built a diversified pipeline of psychedelic product candidates that target mental health disorders that we believe have significant unmet medical need. Our in-house programs include:

- VLS-01 (N,N-Dimethyltryptamine (“DMT”)) for treatment-resistant depression (“TRD”);
- EMP-01(R-3,4-methylenedioxy-methamphetamine ("R-MDMA")) for social anxiety disorder (“SAD”); and
- A drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD

We believe psychedelics are emerging as novel breakthrough therapies for mental health disorders, such as depression, supported by growing scientific evidence, recent regulatory advancements and increasing patient and physician acceptance. Clinical studies have demonstrated the potential safety and efficacy profile of psychedelics, particularly their rapid onset of effect and sustained efficacy after a short course of administration. We believe these programs, which include both novel molecular entities and optimized variants of known compounds, have the potential to address significant unmet needs in mental health treatment.

Our commitment to innovation extends to early-stage drug discovery through our discovery platform. Intellectual property development has been essential to our strategy since inception, particularly through key investments in novel chemical entity ("NCE") development. We have made substantial progress in our drug discovery efforts to date, synthesizing and screening more than 750 compounds and identifying novel scaffolds that display potential in targeting mental health disorders.

Beckley Psytech Strategic Investment

Beckley Psytech Limited ("Beckley Psytech") is a private clinical-stage biopharmaceutical company developing psychedelic product candidates designed to be rapid-acting and short-duration. Beckley Psytech’s two investigational compounds are BPL-003, 5 Methoxy N,N-dimethyltryptamine ("mebufotenin") benzoate, for TRD and alcohol use disorder ("AUD"), and ELE-101, psilocin, for the treatment of major depressive disorder ("MDD"). In January 2024, made a strategic investment in Beckley Psytech, resulting in an approximate one third ownership stake with 1:1 warrant coverage at a 30% premium on the primary issuances. We hold a time-limited right of first refusal on a future sale of the company and an indefinite right of first negotiation for BPL-003 and ELE-101. Additionally, we agreed to collaborate on commercial and market access activities in preparation for potential commercialization. Our financial interest in the product candidates of Beckley Psytech is limited to the potential appreciation of our equity interest.

Recognify Life Sciences Strategic Investment

Recognify Life Sciences, Inc. ("Recognify"), a company in which we have a 51.9% strategic investment, is developing RL-007, an investigational pro-cognitive neuromodulator for the treatment of cognitive impairment associated with schizophrenia (“CIAS”). Currently, there are no approved therapies for CIAS.

IntelGenx Corp. Acquisition

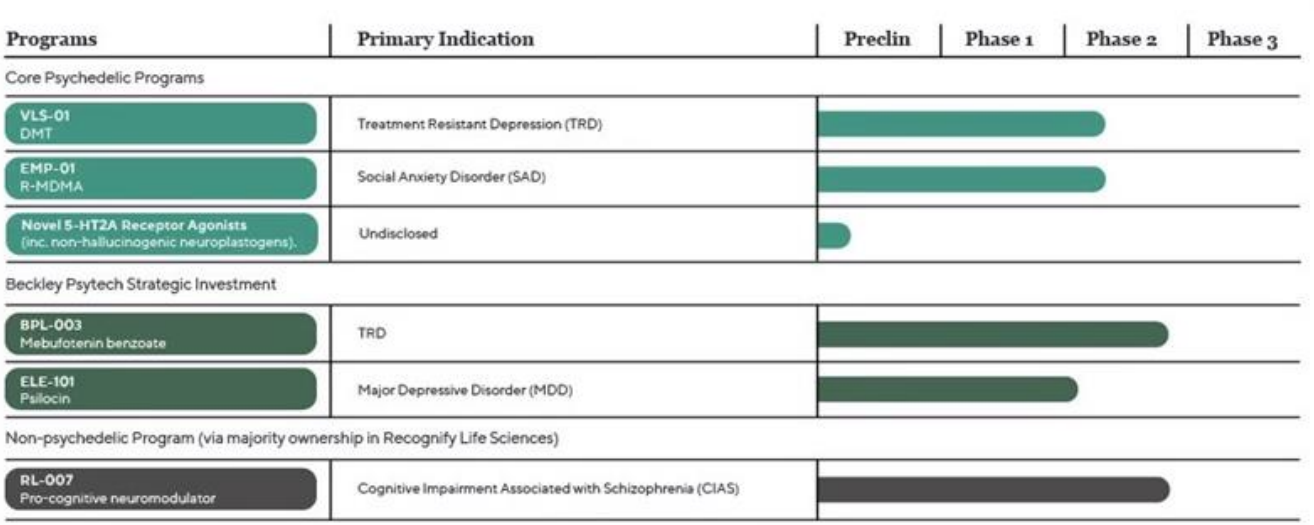
In October 2024, we acquired all of the issued and outstanding shares of IntelGenx Corp. ("IGX"), a subsidiary of IntelGenx Technologies Corp. ("IntelGenx"), following the approval and vesting order obtained by IGX on September 30, 2024 from the Superior Court of Québec (Commercial Division) issued in connection with the proceedings instituted pursuant to the Companies' Creditors Arrangement Act. IntelGenx is a drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and for our development candidate, VLS-01. The acquisition was structured as a credit bid, whereby we agreed that our senior secured debt in IGX was discharged in exchange for IGX shares. No Company equity or cash was exchanged in connection with this transaction.

Compass Pathways Investment

COMPASS Pathways plc ("COMPASS") is a mental health care company dedicated to pioneering the development of a new model of psilocybin therapy with its product COMP360. We first acquired an investment in COMPASS in December 2018 with additional investments through 2021. We currently hold 6,905,774 shares or approximately 7.5% ownership of COMPASS and it is a potential source of non-dilutive funding, subject to market conditions.

Our Pipeline

Our pipeline encompasses product candidates across multiple neuropsychiatric indications including depression, anxiety and CIAS. The table below summarizes the status of our product candidate portfolio, including those in development by the companies in which we are invested, as of the date of this Form 10-K.



The following details our key psychedelic programs, strategic investments and non-psychedelic program, recent advancements in our ongoing clinical trials and upcoming milestones, as applicable:

Psychedelic Programs & Strategic Investments

VLS-01: DMT for TRD

- **Product Candidate Concept:** VLS-01 is an investigational proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT) applied to the buccal surface, being developed for the treatment of people suffering from treatment-resistant depression (TRD). Pharmacologically, VLS-01 is a partial to full agonist of the $5HT_{1/2/6/7}$ receptors and is being developed to potentially offer rapid, robust, and durable efficacy with a favorable safety profile. VLS-01 has been modelled on a short-duration interventional psychiatry treatment paradigm, positioning it for integration into existing care models. In a third-party study, intravenous ("IV") DMT administration has resulted in rapid-acting antidepressant effects in patients with MDD.
- **Disease Overview:** Depression is a mood disorder that affects one's thoughts, behaviors and emotions often causing a prolonged depressed mood and other symptoms severely impacting an individual's ability to live a normal life. Of the estimated 300 million people who suffer from depression worldwide, 50% have depression which is treatment resistant. TRD

occurs when someone with depression does not experience symptom improvement, despite trying at least two different antidepressants.

While there are a wide range of available pharmacological therapies for depression, including SSRIs, SNRIs, and atypical antipsychotics, these drugs have significant limitations for many patients, including slow onset of effect, inadequate response, and significant side effects. Given the limitations of existing therapeutic treatments, there continues to be a high unmet need for antidepressants that provide faster onset of effect, greater efficacy, higher remission rates, and improved tolerability.

- **Recent Advancements:** : In August 2024, we announced positive topline results from the Phase 1b trial, which was designed to evaluate the relative safety, tolerability, pharmacokinetics ("PK") and pharmacodynamics ("PD") of VLS-01 compared to IV DMT. The single center, open-label study enrolled a total of 17 healthy participants, each of whom received a single dose of IV DMT followed by 3 different doses of VLS-01 20mg (N=8), 60mg (N=6), 120mg (N=14) or 160mg (N=16)-with a 28-day washout window between administrations. Peak plasma concentrations ("Cmax") were dose-proportional and comparable between the higher VLS-01 doses (120mg and 160mg) and the 30mg IV DMT dose. Peak plasma concentrations were achieved within 30-45 minutes ("Tmax") and dose-dependent, and robust subjective effects, assessed by the Subjective Intensity Rating Scale ("SIRS"), were seen at the 120mg and 160mg doses. In the 120mg dose cohort: 13/14 participants achieved SIRS scores greater than seven out of ten, and these subjective effects were fully resolved by 120 minutes. VLS-01 demonstrated a favorable safety profile and was well tolerated with all adverse events classified as either mild or moderate, and most resolving on the day of dosing. The most common treatment-emergent adverse events ("TEAEs") were headache, dissociation, euphoric mood and nausea.

  In March 2025, we announced that the first patient has been dosed in the Elumina trial, the randomized, double-blind, placebo-controlled Phase 2 study of VLS-01, which is designed to assess the safety and efficacy of repeated doses in patients with TRD. We anticipate reporting topline data for the Elumina study in the first quarter of 2026. The Elumina trial will consist of two treatment periods. In the first treatment period, approximately 142 patients will be randomized 1:1 to receive a 120mg dose of VLS-01 or placebo on Day 1, followed by a second dose of the same intervention at Week 2. The primary endpoint is the change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 4. The last double-blind assessment visit will be at Week 14. The first treatment period will provide 12 weeks of blinded durability data following two doses of VLS-01 administered in a placebo-controlled fashion.

  The second treatment period starts at Week 14 and will explore the response to two different dose levels of VLS-01. Patients will be randomized 1:1 to receive a third dose of either 60mg or 120mg of VLS-01. Final safety and efficacy assessment will be conducted two weeks after administration of the third dose.

  We anticipate reporting topline data for the Elumina study in the first quarter of 2026.

EMP-01: R-MDMA for SAD

- **Product Candidate Concept**: EMP-01 is an oral formulation of an R-MDMA that demonstrated a unique, dose-dependent subjective effect profile in a Phase 1 trial that was generally found to be more similar to classical psychedelics than to racemic MDMA.
- **Disease Overview:** Anxiety disorders are the most common mental health disorders worldwide, affecting how one experiences worry, fear and anxiety in everyday situations. SAD is an area of high unmet medical need with approximately 18 million people currently diagnosed and no novel molecules approved in over two decades.
- **Recent Advancements**: In January 2025, we initiated an exploratory, randomized, double-blind, placebo-controlled Phase 2 study in the United Kingdom to assess the safety, tolerability and efficacy of EMP-01 in adults with SAD. We expect to randomize the first patient in the second quarter of 2025 and to report topline data from the trial in the first quarter of 2026.

Novel 5-HT2A Receptor Agonists (including non-hallucinogenic neuroplastogens)

- **Product Candidate Concept:** EGX-A and EGX-B are lead candidates from our internal drug discovery engine, which were discovered using an artificial intelligence/machine learning-driven approach. They are psychedelic-like with novel, non-tryptamine structures with differentiated 5-HT receptor pharmacology compared to traditional psychedelics.
- **Recent Advancements:** As part of our continued drug discovery efforts, novel 5-HT2A receptor agonists were discovered that maintain non-hallucinogenic potential based on their inability to fully-substitute for a traditional psychedelic in rodent drug discrimination studies. These differentiated 5-HT2A receptor agonists are being further optimized and studied in a series of animal models to assess therapeutic potential.

BPL-003: Mebufotenin benzoate for TRD and AUD (via Strategic Investment in Beckley Psytech)

- **Product Candidate Concept**: BPL-003 is a dry powder, intranasal formulation of the benzoate salt form of mebufotenin, a psychoactive indolealkylamine derivative of tryptamine. Mebufotenin is a serotonergic psychedelic due to its ability to bind to

a variety of serotonin ("5-HT") receptors where it predominantly acts as an agonist. Its agonist actions at serotonin 1A ("5-HT_{1A}") and serotonin 2A ("5-HT_{2A}") receptors are considered to be the most important for the majority of its reported effects.

- **Disease Overview**: See "— VLS-01 – Disease Overview" for an overview of TRD

  AUD is a medical condition characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences. The World Health Organization ("WHO") estimates that around 400 million people suffer with AUD worldwide, with around 3 million deaths each year attributed to the harmful use of alcohol. Currently available pharmacological treatment options are not very effective and some people with alcohol use disorder who wish to abstain from, or reduce, alcohol consumption do not achieve their treatment goal with currently approved treatment options. This contributes to an unmet need for more effective medical treatments.

- **Recent Advancements:** BPL-003 is currently being investigated as a treatment for people with TRD, with on-going Phase 2a open-label studies and an on-going Phase 2b double-blind, randomized, controlled study as well as an open-label extension study. In addition, Beckley Psytech recently completed an open-label Phase 2a study of BPL-003 in people with moderated to severe AUD.

  Phase 2a study in TRD: In March 2024, Beckley Psytech announced initial results from Part 1 of the on-going Phase 2a open-label study in patients with moderate to severe TRD. The Phase 2a study investigated the safety, tolerability and efficacy of a single 10mg dose of BPL-003 alongside psychological support in patients who were not taking concomitant antidepressants. 12 subjects were dosed, and 11 met the criteria for per-protocol analysis. Patients were followed for 12 weeks post-dosing, with assessments conducted at multiple points throughout the study. Efficacy was assessed using the MADRS. Initial analysis showed that a single dose of BPL-003 induced a rapid antidepressant response (≥50% reduction in MADRS score) in 55% of patients on the day after dosing. The antidepressant effect was durable, with the 55% response rate maintained at weeks 4 and 12. There were 55% of patients in remission (MADRS score ≤10) at Week 4 and 45% in remission at Week 12.BPL-003 demonstrated a promising safety profile and was well tolerated. Adverse events ("AEs") were predominantly mild or moderate and the most common (>10%) AEs were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings. No serious AEs were reported. The acute effects of BPL-003 resolved on average in less than two hours. These data suggest that BPL-003 could offer a shorter treatment time when compared to other psychedelic treatments currently in development.

  Topline results from the Part 2 extension of the Phase 2a open-label study, assessing the safety and efficacy of BPL-003 co-administration in patients with TRD who are on stable doses of oral antidepressants, is anticipated in the second quarter of 2025.

  Phase 2b study in TRD: In March 2025, Beckley Psytech announced that it has completed patient enrollment in the eight-week, core, randomized, quadruple-masked, controlled Phase 2b study of BPL-003 for patients with TRD. The study is investigating the effects from a single 12mg or 8mg dose of BPL-003 against a sub-perceptual dose of 0.3mg in 196 patients with TRD. Efficacy will be assessed by masked raters using the MADRS scale at several time points with the primary endpoint at Week 4 and final assessment at Week 8. Topline results from the core stage of the study are expected in mid-2025.

  The eight-week, open-label, extension stage of the Phase 2b clinical trial continues to enroll patients to evaluate the safety and efficacy of a second high dose of BPL-003 administered after the completion of the core stage of the trial.

  Phase 2a study in AUD: In January 2025, Beckley Psytech announced positive topline findings from its open-label Phase 2a study of BPL-003 in 12 patients with moderate-to-severe AUD. The study evaluated the safety, tolerability, pharmacodynamic effects and impact on alcohol use of a single dose of BPL-003 in combination with relapse prevention cognitive behavioral therapy. Initial data showed that (i) a decrease in the mean number of alcohol units per day from 9.3 alcohol units per day in the 12 weeks prior to dosing to 2.2 alcohol units per day at 12 weeks post-dosing was observed (ii) a decrease in the mean percentage of Heavy Drinking Days from 56% in the pre-dose period to 13% at the end of the study was observed, (iii) an increase in the mean number of abstinent days from 33% to 81% was observed and (iv) 50% of participants remained completely abstinent during the 12-week follow-up period following a single dose. BPL-003 was also well-tolerated with adverse events being reported as mild or moderate and no serious or severe adverse events reported, and with most patients assessed as ready for discharge within approximately 2 hours following dosing. Beckley Psytech plans to evaluate future development options for BPL-003 in substance use disorders.

ELE-101: Psilocin for MDD (via Strategic Investment in Beckley Psytech)

- **Product Candidate Concept:** ELE-101is the benzoate-salt form of psilocin, the active metabolite of psilocybin, which is being evaluated as an IV formulation. ELE-101 is a serotonergic psychedelic, and as such, primarily acts as a partial agonist of the 5-HT2A receptor. Psilocin plasma concentrations are highly correlated with serotonin 5-HT2A receptor occupancy and corresponding psychedelic effect. Studies using oral psilocybin have shown its therapeutic utility and have begun exploring its mechanism of action. However, they also highlighted that the conventional oral formulation has its limitations; PK variability,

prolonged duration of treatment effect and difficulty in optimizing or halting the treatment. IV delivery of psilocin enables consistent drug concentrations to be achieved rapidly and in a controlled manner.

- **Disease Overview**: MDD is a common and serious mood disorder that negatively affects how a person feels, thinks and acts. It is estimated that nearly 300 million people around the globe have depression, with around 52 million people suffering from the condition in Europe and the US combined. Treatment for depression usually involves a combination of lifestyle changes, talking therapies and medicines but, for many patients, even the best current medicines either do not work, or have side effects that leave them not feeling like themselves, or unable to experience life to the fullest.
- **Recent Advancements:** In December 2024, Beckley Psytech, announced topline results from its open-label Phase 2a study of ELE-101 in six patients with MDD. The small proof-of-concept study evaluated the safety, tolerability, subjective effects and efficacy of a single intravenous dose of ELE-101 delivered via a 10-minute infusion. According to Beckley Psytech's announcement, initial data showed that (i) a rapid and clinically significant meaningful antidepressant response was observed in the majority of patients, with these effects sustained in the four subjects that were evaluable at 3 months, (ii) a 25 point mean reduction in scores on the MADRS was observed the day after dosing, (iii) MADRS scores of 10 or less (considered as remission) were observed in four of six subjects the day after dosing, (iv) a greater than 20 point reduction in MADRS scores was observed at all time points through to 3 months after dosing, with MADRS scores of 10 or less observed for all four subjects evaluable at day 90 after dosing. According to the announcement, ELE101 was also well-tolerated with mostly mild, transient adverse events and no serious or severe AEs reported, and with acute effects resolved, and patients deemed ready to be discharged, within a mean time of approximately 2 hours. Beckley Psytech anticipates that further data will be available in 2025 and they will be used to inform the future clinical development of ELE-101.

Non-Psychedelic Program

RL-007: Pro-cognitive neuromodulator for CIAS (via Strategic Investment in Recognify)

- **Product Candidate Concept:** RL-007 is an orally bioavailable compound that has demonstrated pro-cognitive effects in multiple pre-clinical and clinical studies, including two Phase 1 and two Phase 2 trials. Although the precise molecular target and mechanism of action for RL-007 has not yet been fully elucidated, RL-007 has been demonstrated to modulate the cholinergic, glutamatergic and GABA neurotransmitter systems. Overall, RL-007 putatively alters the excitatory/inhibitory balance in the brain. The compound has been assessed in ten completed Phase 1 and Phase 2 clinical trials. To date, over 500 participants have been dosed with no evidence of safety issues. Recognify is initially developing this compound for the treatment of CIAS.
- **Disease Overview:** Schizophrenia is a severe mental health disorder, impacting 24 million people worldwide, that impairs one's thought processes, perceptions, emotional responsiveness and social interactions. CIAS refers to the deficits in cognitive function commonly experienced by individuals with schizophrenia. These impairments affect key domains such as attention, memory, executive function, processing speed, and social cognition, significantly impacting daily life, employment, and social interactions. CIAS is a core and persistent feature of schizophrenia, often present before the onset of full psychotic symptoms and remaining throughout the illness. Current antipsychotic medications primarily target psychotic symptoms and offer little relief for CIAS.
- **Recent Advancements:** Recognify is currently conducting a Phase 2b proof-of-concept clinical trial in the U.S. for RL-007 in 234 patients with CIAS. Recognify anticipates reporting topline results from this study in mid-2025.

Competition

The pharmaceutical industry is highly competitive, with new approaches and technologies regularly emerging. We face competition across our current programs and expect to face competition with any future programs we may seek to develop and/or commercialize from major pharmaceutical, biotechnology, specialty pharmaceutical and generic pharmaceutical companies, among others. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. In addition, programs that we currently believe to be complementary may eventually become competitors.

Many of the companies with which we compete or with which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do and may already have established markets for their products. Accordingly, our potential competitors may succeed in obtaining FDA or other regulatory approval for alternative or superior products. Our competitors also may compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs. In addition, competitors may have higher name recognition and more extensive collaborative relationships. Mergers and acquisitions within the industry may result in greater resources being concentrated among a small set of competitors. Smaller or emerging earlier-stage companies may also prove to be

significant competitors, particularly if they have collaborations with larger, established companies. We are aware that a number of companies are increasing their efforts in discovery of non-traditional alternative compounds including psychedelics.

The commercial opportunity for our product candidates could reduce or be eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Furthermore, we may also face competition from 501(c)(3) non-profit -=medical research organizations, including the Usona Institute and the Multidisciplinary Association for Psychedelic Studies ("MAPS"). Such non-profit organizations may be willing to provide products at cost or for free which could significantly disrupt the potential market for our products. Our competitors also may obtain FDA or other regulatory approval for their products faster than we may obtain approval for ours, which could result in our competitors establishing a market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, as well as the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Depression

Multiple therapies for depression exist, including common pharmacological treatments such as anti-depressants and psychosocial interventions such as cognitive based therapy. There are also non-pharmacological, somatic treatments for depression such as electroconvulsive therapy and transcranial magnetic stimulation, among others. However, these current therapies are ineffective or inadequately effective for a significant portion of patients. This treatment-resistant subset of depression is our initial therapeutic focus for several of our compounds. For TRD there are currently only two pharmacological treatments approved in the United States: (i) SPRAVATO (S-ketamine) nasal spray, an NMDA receptor antagonist, approved by the FDA in March 2019 and marketed by Janssen Pharmaceutical Companies of Johnson & Johnson, and (ii) a fixed dose combination of olanzapine and fluoxetine hydrochloride, which are individually available generically. In addition, there have been recent developments in the treatment of MDD, including AUVELITY, a therapeutic marketed by Axsome Therapeutics, which was recently approved by the FDA in August 2022. Psychosocial interventions and non-pharmacological, somatic treatments may also be used for patients. We are aware of several other biopharmaceutical companies with therapies in development for TRD and MDD including, GH Research, Cybin, Neumora Therapeutics, Alto Neuroscience, Neurocrine Biosciences, as well as COMPASS, in which we hold an equity stake.

Cognitive Impairment Associated with Schizophrenia

We are not aware of any pharmacological treatments approved for CIAS. While antipsychotics are most commonly used to treat psychotic symptoms of schizophrenia, these medications fail to address the cognitive and negative symptoms of schizophrenia and are often associated with severe dose limiting effects. Furthermore, over 50 assets in development for CIAS have been discontinued or are inactive, indicating the complexity of successfully developing a therapy for this condition. We are aware of biopharmaceutical companies with therapies in development for CIAS, including Alto Neuroscience. Other companies with therapies in development in schizophrenia not focused on CIAS that we are aware of include Newron Pharmaceuticals and AbbVie .

Anxiety

Anxiety disorders are generally treated with medication, psychotherapy or both. Treatment often involves the use of antidepressants. However, these typically have a slow onset of action and a number of side effects, such as sexual dysfunction, drowsiness and weight gain. Benzodiazepines are also used to treat anxiety and can offer rapid reduction of symptoms, but their long-term use is associated with the development of tolerance, respiratory depression, drug dependence and sedative side effects.

We are aware of several biopharmaceutical companies with therapies in development for anxiety disorders including VistaGen Therapeutics, Engrail Therapeutics, Neuphoria Therapeutics, MindMed, Cybin, Intracellular-Therapies and Lykos Therapeutics.

Overview of our Intellectual Property

Our success depends in part on our ability to obtain and maintain protection of intellectual property, particularly patents, in the United States and other countries with respect to product candidates and technology that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business for which we do not consider patent protection appropriate. The intellectual property covering the technologies and product candidates related to our programs for partially owned platform companies are handled directly by the applicable platform companies, and we are not actively involved in the management of such intellectual property. For information regarding risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

As of March 2025, our intellectual property portfolio includes 46 issued U.S. patents, 70 issued non-U.S. patents, 47 pending U.S. patent applications, 128 pending non-U.S. patent applications, 7 pending U.S. provisional applications, and 35 PCT applications. Our intellectual property portfolio for our key psychedelic programs, strategic investments and non-psychedelic program are summarized in the table below and described further for certain programs. In addition, we have, and may continue to, enter into collaboration and licensing arrangements for research and development, manufacturing, and commercialization activities with counterparties for the development and commercialization of its product candidates.

Lead Compound	Issued		Pending	
	MoT	CoM	MoT	CoM
VLS-01	✓	✓	✓	✓
EMP-01	✓	✓	✓	✓
EGX-A & EGX-B	✓	✓	✓	✓
BPL-003	✓	✓	✓	✓
ELE-101	✓		✓	
RL-007	✓	✓	✓	✓

CoM: Composition of matter claims for drug product or formulation
MoT: Method of treatment claims

A description of our patents for our key psychedelic programs, strategic investments and non-psychedelic program as of December 31, 2024, follows below:

VLS-01

Atai Therapeutics, Inc. owns two issued U.S. patents, three pending U.S. patent applications and three pending PCT patent applications, one pending U.S. provisional patent application and thirty-one pending foreign patent applications in Argentina, Taiwan, Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russian Federation and UAE, covering (i) DMT compositions exhibiting unique PK profiles following transmucosal administration (ii) new DMT salts and polymorphic forms, including DMT succinate, (iii) DMT parenteral formulations, and (iv) oral transmucosal films of DMT. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2042 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Atai Therapeutics, Inc. owns three issued U.S. patents, four pending U.S. patent applications, seven pending PCT patent applications, one pending U.S. provisional patent application and twenty pending foreign applications in Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russian Federation, UAE, Argentina, and Taiwan, covering novel analogues, products and conjugates of dimethyltryptamine, methods and pharmaceutical compositions thereof. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2042 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EMP-01

EmpathBio, Inc. owns three issued U.S. patents, nine pending U.S. patent applications, seven pending foreign patent applications in Canada, Europe and Mexico, and nine pending PCT patent applications, covering MDMA enantiomers and processes for the preparation of

MDMA, its enantiomers and derivatives thereof. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2042 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. EmpathBio, Inc. owns two pending U.S. patent applications, and two pending PCT patent applications covering salts of R-MDMA and polymorphic forms and compositions comprising R-MDMA and methods of treating with the same. Any patents issuing from these pending patent applications, if granted, are expected to expire between 2043 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. EmpathBio, Inc. owns two pending U.S. patent applications and three pending PCT patent applications covering uses of MDMA for treating stress related disorders, increasing exposure of R-MDA, and modulating aggression responses. Any patents issuing from these pending patent applications, if granted, are expected to expire between 2043 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EGX-A & EGX-B

Atai Therapeutics, Inc. owns two issued U.S. patents, four pending U.S. patent applications, five pending PCT patent applications, and eighteen pending foreign patent applications in Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia and UAE and three pending U.S. provisional patent applications covering novel 5-HT2A agonists and methods of using the same. These issued patents and any patents issuing from these pending patent applications, if granted, are expected to expire between 2041 and 2044. Atai Therapeutics, Inc. owns one pending PCT patent application covering non-hallucinogenic 5-HT2A agonists. Any patents issuing from this application, if granted, are expected to expire in 2044.

BPL-003

Beckley Psytech owns two issued U.S. patents, fifteen foreign issued patents in Europe, three issued patents in the United Kingdom, one issued Chinese patent, four pending U.S. patent applications, thirteen pending foreign patent applications across Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand, four pending PCT patent applications and numerous pending United Kingdom and U.S. priority/provisional patent applications covering the benzoate salt of 5-methoxy-N,N-dimethyltryptamine (mebufotenin), methods of synthesis, methods of use, crystalline forms and formulations thereof. The aforementioned issued patents are expected to cover BPL-003 until at least 2041 in the respective jurisdictions. Atai Therapeutics, Inc. has a strategic investment in Beckley Psytech to accelerate the clinical development of short-duration psychedelics.

ELE-101

Beckley Psytech owns two issued U.S. patents, three pending U.S. patent applications, one pending PCT patent application and ten pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand, and numerous pending United Kingdom and U.S. priority/provisional patent applications covering the benzoate salt of 4-hydroxy-N,N-dimethyltryptamine (psilocin), methods of synthesis, methods of use, crystalline forms and formulations thereof. Beckley Psytech also co-owns with Board of Supervisors of Louisiana State of University and Agricultural and Mechanical College one pending U.S. patent application and one pending foreign patent application in Europe covering methods of use of psilocin and 3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate (psilocybin). Atai Therapeutics, Inc. has a strategic investment in Beckley Psytech to accelerate the clinical development of short-duration psychedelics.

RL-007

Recognify in-licenses twelve issued U.S. patents and 36 foreign issued patents in Europe, Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand and Russia, covering RL-007, including the pharmaceutical composition of and methods of using RL-007. The patents licensed to Recognify are expected to expire between 2026 and 2034, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Patents

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. With regard to our U.S. provisional patent applications, if we do not file any corresponding non-provisional patent applications within 12 months of the provisional patent application filing date, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. All taxes, annuities or maintenance fees for a patent, as required by the United States Patent and Trademark Office ("USPTO") and certain foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent. Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to

conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trade Secrets and Proprietary Information

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with our employees, consultants, and independent contractors. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information, and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. See “Risk Factors—Risks Related to our Intellectual Property.”

Government Regulation and Product Approval

The FDA, the U.S. Department of Health and Human Services Office of Inspector General, Centers for Medicare and Medicaid Services ("CMS"), the U.S. Drug Enforcement Administration ("DEA"), and comparable regulatory authorities in state and local jurisdictions and in other countries impose requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state, local and foreign entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of required non-clinical laboratory tests, animal studies and formulation studies in accordance with FDA’s good laboratory practice (“GLP”) requirements and other applicable regulations;
- submission to the FDA of an investigational new drug application ("IND") which must become effective before human clinical trials may begin;
- approval by an institutional review board (“IRB”) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (“GCP”) requirements to evaluate the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application (“NDA”) after completion of all pivotal trials;
- payment of user fees for the FDA review of the NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice (“cGMP”) requirements to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity;
- potential FDA audit of the non-clinical and/or clinical trial sites that generated the data in support of the NDA, and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND must become effective before human clinical trials may begin. An IND is a request to the FDA for allowance to initiate a clinical trial in the

United States. The central focus of an IND submission is on the non-clinical studies supporting the safe conduct of proposed clinical studies, the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the safety results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

An independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials, with objectives around demonstrating proof-of-mechanism, proof-of-concept, or dose finding.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to evaluate the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA to demonstrate substantial evidence of efficacy.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in

accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, new molecular entity NDAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Once an NDA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once an NDA has been accepted for filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an NDA to an advisory committee for review before deciding on the application. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA and conducts any required inspections of the manufacturing facilities where the product candidate and/or its drug substance will be produced, the FDA will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as a clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the product is distributed and used in a manner such that benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or

elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may withdraw or limit further marketing of the product based on the results of such post-marketing studies.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of product candidates that meet certain criteria. For example, drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track-designated product candidate has opportunities for more frequent interactions with the review team during product development, and once submitted, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may also designate a product candidate as a "breakthrough therapy" if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast-track designation features, as well as more intensive FDA interaction and guidance.

An NDA may be eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide significant improvement in safety or efficacy compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for standard review of new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical studies, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to verify and describe the clinical benefit predicted by the surrogate or intermediate endpoint, and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are also continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the

approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA") which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity authorized under the FDCA. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of existing exclusivity or an available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

DEA Regulation

The Controlled Substances Act ("CSA") establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control and handling and distribution of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. They may be distributed for research uses under strict controls and approval by the DEA. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as security cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also regulate controlled substances.

After FDA market approval there is a process triggered for rescheduling controlled substances. At the initiation of review, the DEA, U.S. Department of Health and Human Services ("HHS") (via the FDA), or an external petitioner can initiate a scheduling review to evaluate an eight-factor analysis assessing abuse potential, pharmacology, public health risk, and dependence liability. HHS then makes a scheduling recommendation to the DEA, which reviews HHS's findings, publishes a proposed rule in the Federal Register, and solicits public comments before finalizing the new schedule. This process can take several months, but there is a process for an interim final rule for expedited action to prevent delays in patient access. This law requires the DEA to issue an interim final rule within 90 days of FDA approval, allowing the drug to be prescribed while final scheduling is completed.

Foreign Government Regulation

Our product candidates are subject to similar laws and regulations imposed by jurisdictions outside of the United States, and, in particular, the EU, governing, among other things, clinical trials, marketing authorization ("MA"), applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similarly to the United States, the various phases of nonclinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set

forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, nonclinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Cooperation and Development ("OECD") requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on GCPs as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System ("CTIS"), which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol, and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025 and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice ("GMP"). Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MA" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Product for Human Use ("CHMP") of the European Medicines Agency ("EMA") and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as: (i) medicinal products derived from biotechnological processes, such as genetic engineering, (ii) designated orphan medicinal products, (iii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, or auto-immune diseases and other immune dysfunctions and viral diseases and (iv) advanced therapy medicinal products ("ATMPs") such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the above described procedures, before granting the MA, the competent authorities make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Data and marketing exclusivity

In the EU, new product candidates authorized for marketing, or reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Controlled Substances

Controlled substances are not regulated at EU level and the EU legislation does not establish different classes of narcotic or psychotropic substances. However, the United Nations ("UN") Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971 ("together, "the UN Conventions") codify internationally applicable control measures to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The individual EU member states are all signatories to these UN Conventions. All signatories have a dual obligation to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence.

The UN Conventions regulate narcotic drugs and psychotropic substances as Schedule I, II, III, IV substances with Schedule II substances presenting the lowest relative risk of abuse among such substances and Schedule I and IV substances considered to present the highest risk of abuse.

The UN Conventions require signatories to require all persons manufacturing, trading (including exporting and importing) or distributing controlled substances to obtain a license from the relevant authority. Each individual export or import of a controlled substance must also be subject to an authorization. Before the relevant authority can issue an export authorization for a particular shipment, the exporter must

provide the authority with a copy of the import authorization issued by the relevant authority of the importing country. Implementation of the obligations provided in the UN Conventions and additional requirements are regulated at national level and requirements may vary from one member state to another.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAA must include a risk management plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA") which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

Following the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom ("UK") is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK, however, new legislation such as the (EU) CTR is not applicable in Great Britain.

Under the Medicines and Medical Devices Act 2021, the Secretary of State or an 'appropriate authority' has delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA"), is the UK's standalone medicines and medical devices regulator. As a result of the Ireland/Northern Ireland protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland, together, Great Britain ("GB"); broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from pre-existing EU legislation (as implemented into UK law, through secondary legislation). The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026.

MAs in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder opted-out. Under the terms of the Windsor Framework, these MAs became valid for the whole of the UK from January 1, 2025. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, since Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP") when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulators in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update an MA in the UK or Great Britain. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60-day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals. In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK within three (3) years shall cease to be in force.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, state, federal and foreign anti-kickback, fraud and abuse, false claims and transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other healthcare professionals. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and/or individual imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations and imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate

reductions of Medicare payments to providers, which was temporarily suspended from May 1, 2020 through March 31, 2022. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation intended to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, therefore, have a negative impact on our financial results.

Health Technology Assessment ("HTA") of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

On December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022, and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Environmental, Health and Safety

We are also subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the generation, handling, use, storage, treatment, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations cannot be eliminated. Certain of these laws also can result in liability without regard to fault or historic legality of actions. Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent, and we may incur substantial costs in order to comply with such current or future laws and regulations.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including health, data privacy, and consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, federal and state laws and regulations, including data breach notification laws, health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data, and may apply to our business. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital Management

As a company focused on the treatment of mental health disorders, we are dedicated to pioneering the development of highly effective mental health treatments that transform patient outcomes. Our team is the key to our success, and we believe it is essential to invest in building an engaged, diverse, supported, and incentivized workforce who can help us achieve our vision of creating new possibilities for everyone, everywhere struggling with a mental health disorder.

As of December 31, 2024, we had 54 full-time employees and nine contractors or consultants doing regular work for us. Of our full-time employees, 22 focus on driving forward research and development programs, either directly or through our subsidiaries. Others provide strategic business development, finance, and executive leadership expertise, as well as operational, communications, legal and administrative services. Approximately two-thirds of our employees are located in the U.S., with the remainder split between the United Kingdom and Germany.

In 2024 we revised our core atai values. Our evolved values are: Rooted in Purpose, See Opportunities Where Others See None, Work the Problem and Keep it Simple. Our human capital philosophy is deeply rooted in these values, which form the core of everything from performance management cycle to hiring decisions. See "—Professional Development and Performance Management" and "—Core Values and Ethics" below, for more information.

We have no collective bargaining agreements with our employees, and we have not experienced any significant work stoppages.

Recruiting

We remain committed to a talent acquisition strategy that prioritizes agility and alignment with our organizational goals. Our human resources team and hiring managers continue to take the lead in recruitment, leveraging their extensive networks and expertise to meet current hiring objectives. By focusing on delivering a seamless recruiting process and an outstanding candidate experience, we believe our approach attracts exceptional talent. Looking ahead, we are actively exploring innovative methods to connect with highly skilled professionals, keeping our recruitment efforts forward-thinking and impactful.

We are committed to attracting and retaining top performing team members. We focus on creating a dynamic, vibrant, values-based culture that allows for autonomy, growth and impact while also offering a competitive total rewards package.

Professional Development and Performance Management

We have a bi-annual performance management cycle whereby employees are rated on both "what" they delivered (measured against agreed objectives and goals) and "how" they delivered (measured against the four core atai values and related behaviors). These reviews include self-evaluation, peer and manager feedback. The feedback focuses on strengths and opportunities for improvement to enable the professional development of all team members.

Core Values and Ethics

We have also developed a set of indicators of behavior to help staff and managers understand how to best live our values day to day. The core values are as follows:

- **Rooted in Purpose:** We each have a personal 'why' that inspires our commitment to make a meaningful difference to those living with mental health disorders.
- **See Opportunities Where Others See None:** We are trailblazers, thriving in the face of uncertainty and adversity while embracing challenges.
- **Work the Problem:** We are hands-on, resilient, and adaptable, knowing that tackling issues together leads to effective solutions and shared success.
- **Keep it Simple:** We prioritize clarity and simplicity in everything we do, enabling us to focus on what matters to drive meaningful results.

All of our managing directors, supervisory directors, officers and employees are responsible for upholding these values as set forth in our Code of Conduct, which forms the foundation of our policies and practices. Our Code of Conduct is available in the "Governance Overview" section of our website under "Investor - Corporate Governance," which is located at https://ir.atai.com.

Total Rewards and Employee Engagement

To attract and retain top talent, we offer a competitive total rewards package designed to align with market standards and individual performance. Our approach includes a combination of base salary, performance-based bonuses, and employee stock option grants to ensure a well-rounded compensation structure. A portion of every employee's compensation is tied to performance, reinforcing our commitment to rewarding contributions that drive organizational success.

We invest in the professional development of our employees. All of our employees are strongly encouraged to develop personal development plans with their manager in order to define their career goals, and we encourage regular peer and manager feedback. We also offer targeted learning and development opportunities, including team and 1-1 coaching; access to continual growth through online learning platforms; external training where appropriate; and in-house live training, among other opportunities. In addition, to further employee enrichment and engagement, we periodically survey our employees regarding their engagement levels. We use these survey results to determine how we can continue to create work environments that enable and motivate our employees and to develop a positive working culture. We also provide opportunities for our employees to take two working days each year to give back to their communities through volunteering. In addition, we hold regular company-wide team meetings aimed to connect with each other, foster a culture of transparency, receive updates from our management team and to discuss various other initiatives around the Company. We believe these initiatives foster a positive working environment.

Inclusion and Belonging

We believe that an inclusive culture is critical to atai's success. We are proud to promote voices within and outside our organization, regardless of background, and are eager to learn from others' experiences, as we know that an inclusive workforce is a business imperative and key to our long-term success.

Hybrid office culture

As of December 31, 2024, we maintain offices in Berlin and New York to support our flexible, hybrid work culture. While we do not mandate office attendance, we encourage employees to make use of these spaces to foster creativity, cross-functional collaboration, and social connection. Our offices also provide opportunities for informal interactions that can spark innovation and valuable learning experiences, especially for junior team members. This approach ensures our teams have the flexibility to work in a way that best supports their productivity and well-being, while still benefiting from the unique advantages of in-person engagement.

atai Impact

Our philanthropic program, atai Impact, was launched in October 2021 to harness the power of innovative mental health approaches for positive social change. atai Impact is committed to advancing education, expanding access, and supporting the wider ecosystem of mental health care, with an initial focus on psychedelics. The establishment of atai Impact is based on our position that harmonization across commercial and non-profit entities represents the best path forward to address all aspects of the escalating global mental crisis.

Since its inception, atai Impact has announced multiple initiatives, such as the establishment of the atai Fellowship Fund in Psychedelic Neuroscience (the "atai Fellowship Fund") in collaboration with Massachusetts General Hospital's Center for the Neuroscience of Psychedelics. The $2.0 million atai Fellowship Fund has facilitated further research into the potential of psychedelics to address unmet patient needs in mental health and support promising graduate students in furthering their professional careers in this emerging field.

Corporate Information

The statutory seat of ATAI Life Sciences N.V. is in Amsterdam, the Netherlands. Our office address and our principal executive office is located at Wallstraße 16, 10179, Berlin, Germany, and our telephone number is +49 89 2153 9035. Our website address is www.atai.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available for download, free of charge, through our investor relations website at *ir.atai.com* as soon as reasonably practicable after filing such material with the SEC. The information contained on, or that can be accessed from, our website does not form part of this document. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC. Additionally, the SEC maintains a website that contains our reports, proxy and information statements, and other information. The address of the SEC's website is www.sec.gov.

Item lA. Risk Factors

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Form 10-K. The realization of any of these risks and uncertainties could have a material adverse effect on our reputation, business, financial condition, results of operations, growth and future prospects as well as our ability to accomplish our strategic objectives. In that event, the market price of our common shares could decline, and you could lose part or all of your investment. Please also refer to the section titled "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this Form 10-K.

Risks Related to our Financial Position, Need for Additional Capital and Growth Strategy

We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never be profitable.

We are a clinical stage biopharmaceutical company with a limited operating history. We anticipate that we will incur significant losses for the foreseeable future and have incurred losses in each year since our inception. Our net loss attributable to ATAI Life Sciences N.V. stockholders for the years ended December 31, 2024 and 2023 was $149.3 million and $40.2 million, respectively. We have no products that are approved for commercial sale and have not generated any commercial product revenue. We have financed operations predominantly through the sale of equity securities and debt financings. We continue to incur significant research and development and other expenses related to ongoing operations and building our business infrastructure and expect to incur losses for the foreseeable future.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the acceptance of the product by physicians and patients, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. Our growth strategy depends on our ability to generate revenue. In addition, if the number of addressable patients is not as anticipated, the indication or intended use approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Because of the numerous risks and uncertainties associated with the development of drugs and medical devices, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA, the EMA, the Medicines and Healthcare Products Regulatory Authority, ("MHRA)", or other comparable foreign regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our existing product candidates and any other product candidates that we may identify. Even if our existing product candidates or any future product candidates that we may identify are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product and ongoing compliance efforts.

Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, and pursue or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

Our limited operating history may make it difficult for you to evaluate the success of our business and to assess our future viability.

We were founded in 2018 by Christian Angermayer, Florian Brand, Srinivas Rao and Lars Christian Wilde. To date, we have invested most of our resources in developing technology, establishing our platform, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital, building our management team and providing general and administrative support for these operations. We have not yet demonstrated an ability to conduct later-stage clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, conduct sales and marketing activities necessary for successful product commercialization or obtain reimbursement in the countries of sale.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities and may not be successful in such a transition. We also expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

If we are unable to obtain funding when needed and on acceptable terms, we could be forced to delay, limit or discontinue our product candidate development efforts.

Developing biopharmaceutical products is expensive and time consuming, and we expect to require substantial additional capital to conduct research, preclinical studies and clinical trials for our current and future programs, establish pilot scale and commercial scale manufacturing processes and facilities, seek regulatory approvals for our product candidates and launch and commercialize any products for which we receive regulatory approval, including building our own commercial sales, marketing and distribution organization. We regularly assess the ongoing development of our programs and may, from time to time, delay, limit or otherwise discontinue a program in order to allocate resources towards our existing programs, more developed programs or new investments. In addition, in connection with collaboration agreements relating to our programs, we may also be responsible for the payments to third parties of expenses that may, in certain instances, include milestone payments, license maintenance fees and royalties, including in the case of certain of our agreements with academic institutions or other companies from whom intellectual property rights underlying their respective programs have been in-licensed or acquired. Because the outcome of any preclinical or clinical development and regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and potential commercialization of our product candidates and any future product candidates we may identify.

As of December 31, 2024, we had cash and cash equivalents of $17.5 million, restricted cash of $10.0 million and short-term securities of $44.8 million. Based on our current operating plan, we estimate that our existing cash, including proceeds from our public offering of our common shares, marketable securities, and committed term loan funding as of the date this Annual Report on Form 10-K is filed with the SEC will be sufficient to fund operations into 2027. However, our operating plan has, and may continue to change as a result of many factors, some of which may be currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, sales of assets or programs, other sources, such as strategic collaborations or license and development agreements, or a combination of these approaches. We also may opportunistically seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any such additional fundraising efforts for us may divert our management from their day-to-day responsibilities, which may adversely affect our ability to develop and commercialize our product candidates or any future product candidates we may identify and pursue. Moreover, such financing may result in dilution to shareholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. For example, in February 2025, we issued and sold 30,119,048 common shares in an underwritten public offering, at a public offering price of $2.10 per common share. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the time and cost necessary to complete ongoing and planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- the progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities for our ongoing and planned clinical trials, and potential future clinical trials, including progress and related milestones, the failure by third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites, and other circumstances;
- the costs of obtaining clinical and commercial supplies of raw materials and drug products for our product candidates, as applicable, and any other product candidates we may identify and develop;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations (“CMOs”);
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the cash requirements in purchasing additional equity from certain of our atai companies upon the achievement of specified development milestone events;
- the cash requirements of developing our programs and our ability and willingness to finance their continued development;
- the cash requirements of any future acquisitions or discovery of product candidates, including minority equity investments in third parties;

- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates;
- the costs of acquiring, licensing or investing in intellectual property rights, products, product candidates and businesses;
- the costs of maintaining, expanding and protecting our intellectual property portfolio;
- our ability to attract, hire and retain qualified personnel as we expand research and development and our operational and commercial infrastructure; and
- the costs of operating as a public company in the United States and maintaining a listing on the Nasdaq Stock Market LLC ("Nasdaq").

We cannot be certain that additional funding will be available on acceptable terms, or at all. For example, market volatility resulting from, among other factors, military conflicts and related sanctions, such as ongoing conflicts in the Middle East, as well as, Russia's war in Ukraine, or other unknown factors could also adversely impact our ability to access funds as and when needed. If adequate funds are not available to us on a timely basis, we may be required to delay, limit or discontinue one or more research or development programs or the potential commercialization of any approved products or be unable to expand operations or otherwise capitalize on business opportunities, as desired, which could materially affect our business, prospects, financial condition and results of operations.

Raising additional capital, such as through future sales and issuances of our common shares or rights to purchase common shares, including pursuant to our equity incentive plans, may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to current product candidates or to any future product candidates on unfavorable terms.

Unless and until we can generate a substantial amount of revenue from our product candidates, we expect our expenses to increase in connection with our planned operations. In order to accomplish our business objectives and develop our product candidate pipeline, we expect to finance our future cash needs through a combination of public and private equity or debt financings, sales of assets or programs, and other sources, such as strategic collaborations or license and development agreements. Because any decision by us to issue debt or equity securities in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financing transactions. Our supervisory board has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. For example, On July 1, 2022, we filed a registration statement on Form S-3 (File No. 333-265970) with the SEC, declared effective on July 11, 2022 (the "Shelf Registration Statement"), in relation to the registration of common shares, debt securities, warrants and/or units of any combination thereof for the purpose of selling, from time to time, our common shares, debt securities or other equity securities in one or more offerings. Under the Shelf Registration Statement and a prospectus supplement filed on November 10, 2022, we registered $300.0 million of securities, of which $150.0 million was reserved for sales under our at-the-market equity offering program, all of which remained available as of December 31, 2024. In February 2025, under the Shelf Registration Statement and a prospectus supplement filed on February 13, 2025, we issued and sold 26,190,477 common shares in an underwritten offering. The common shares were sold at a public offering price of $2.10 per share, less underwriting discounts and commissions. We received aggregate net proceeds of $51.4 million. In connection with the underwritten public offering, we granted Berenberg Capital Markets LLC (the "Underwriter") an option exercisable for 30 days to purchase up to an additional 3,928,571 common shares from us at the public offering price of $2.10 per share, less underwriting discounts and commissions. The Underwriter exercised its option to purchase all additional shares February 19, 2025, and we received $7.8 million. As a result of this offering, our shareholders experienced significant dilution. As of February 19, 2025, $150.0 million remains allocated and available under our at-the-market equity offering program and approximately $86.8 million remains available and unallocated under our Shelf Registration Statement. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for the common shares. We have also filed a registration statement on Form S-8 registering the issuance of common shares issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, certain of our executive officers, employees and affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common shares. To the extent that we raise additional capital through the sale of equity or convertible debt securities, shareholder ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing shareholders. In addition, the possibility of such issuance may cause the market price of our common shares to decline. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations and liens on our assets, limitations on our ability to acquire, sell or license intellectual property rights, and other operating and financing restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses or other rights on unfavorable terms.

Pursuant to our 2021 Incentive Award Plan ("2021 Incentive Plan") we are authorized to grant various stock-based awards to our executive officers, directors, employees and consultants. If our supervisory board elects in the future to increase the number of shares available for future grant and, in the case of the 2021 Incentive Plan, if our shareholders approve of any such further increase to the overall share limit, our shareholders may experience additional dilution, and our share price may fall.

If we obtain a controlling interest in certain of our existing companies or additional companies in the future, it could adversely affect our operating results and the value of our common shares, thereby disrupting our business.

As part of our strategy, we have and intend to continue to invest in companies that further or complement our strategy and help accomplish our business objectives, which we assess on an ongoing basis. We and our atai companies have also acquired and in-licensed certain of our technologies from third parties, and we may in the future acquire, in-license or invest in additional technology that we believe would be beneficial to our business. Investments in our existing and any future subsidiaries and other companies and the acquisition, in-license or investments in technology involve numerous risks, including, but not limited to:

- risk of conducting research and development activities in new and innovative therapeutic areas or treatment modalities in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition, joint venture, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition; and
- the impact of regulatory reviews and outcome of any legal proceedings that may be instituted with respect to a proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such acquisition, investment or transaction, we might incur costs in excess of what we anticipate, we might delay, limit or otherwise discontinue a program based on our ongoing assessment of our programs, and management resources and attention might be diverted from other necessary or valuable activities, any of which may have an adverse impact on our business, financial condition and results of operations.

As a result of covenants related to our Loan Agreement with Hercules, our operating activities may be restricted and we may be required to repay the outstanding indebtedness in the event of a breach by us, or an event of default thereunder, which could have a materially adverse effect on our business.

In August 2022, we entered into a Loan and Security Agreement, as amended in March 2023, May 2023, August 2024 and January 2025 (collectively, the "Loan Agreement"), with Hercules Capital, Inc., ("Hercules"), pursuant to which we have total borrowing capacity under several tranches of up to $175.0 million aggregate principal (the "2022 Term Loan Facility"). The 2022 Term Loan Facility is secured by a lien on substantially all of our assets, including intellectual property, with certain limited exceptions set forth in the Loan Agreement. The Loan Agreement contains various covenants that may restrict our ability, among other things, to sell, transfer, lease or dispose of certain assets; make material changes to our business; incur indebtedness; encumber or permit liens on certain assets; make certain investments and acquisitions; make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common shares; and enter into certain transactions. Our business may be adversely affected by these restrictions on our ability to operate our business.

In addition, we are required under the Loan Agreement to comply with various covenants and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

We intend to satisfy our current and future debt service obligations with our existing cash, cash equivalents and available for sale securities, potential future product revenues and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing on acceptable terms, or at all, to pay the amounts due under the 2022 Term Loan Facility.

Any breach by us, or any event of default under, our Loan Agreement could result in a material adverse effect on our business, financial condition and operating results.

Our overall value may be dominated by a single or limited number of our atai companies or clinical programs.

A large proportion of our overall value may at any time reside in a small proportion of our atai companies or clinical programs. Accordingly, there is a risk that if one or more of the intellectual property or commercial rights relevant to a valuable business were

impaired, this would have a material adverse impact on our overall value. Furthermore, a large proportion of our overall revenue may at any time be the subject of one, or a small number of, licensed technologies. Should the relevant licenses be terminated or expire this would be likely to have a material adverse effect on the revenue received by us.

In addition, although we do not have a majority interest in certain of our atai companies, such as COMPASS and Beckley Psytech, a large proportion of our overall value may at any time reside in our ownership interest of such companies. Our interest in COMPASS or Beckley Psytech may also be reduced to the extent such company raises capital from additional third-party investors. Accordingly, any material adverse impact on the value of the business of a subsidiary, atai company or a clinical program, could have a material adverse effect on our business, financial condition, trading performance and/or prospects.

Our programs are difficult to value given they are in the development stage.

Investments in early-stage companies, such as ours, are inherently difficult to value since sales, cash flow and tangible asset values are very limited, which makes the valuation highly dependent on expectations of future development, and any future significant revenues, if they arise, would only arise in the medium to longer term and are uncertain. Similarly, investments in companies that are in the development stage, such as ours, are also difficult to value since sales, cash flow and tangible assets are limited, and valuations are still dependent on expectations of future development. For example, we utilize the equity method to account for certain of our atai noncontrolled entities, and we evaluate each of these investments at the end of each reporting period. We present income/losses from equity investments and any impairment related to equity method investments as losses from investments in equity method investees on our consolidated statements of operations, and these evaluations could result in a material impact on our financial statements and results of operations. There can be no guarantee that our valuations of our programs will be considered to be correct in light of the early stage of development for many of these entities and their future performance. As a result, we may not realize the full value of our ownership in such subsidiaries, which could adversely affect our business and results of operations.

Our product candidates represent novel and innovative potential therapeutic areas, and negative perception of any product candidate that we develop could adversely affect our ability to conduct our business, obtain regulatory approvals or identify alternate regulatory pathways to market for such product candidate.

Our product candidates represent novel and innovative potential therapeutic areas, including substances that might be controversial, overlooked or underused. Our success will depend upon physicians who specialize in the treatment of mental health disorders, including depression, substance use disorder, anxiety disorder and other neurological indications targeted by our product candidates, prescribing potential treatments that involve the use of our product candidates, if approved, in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Our product candidates may not be successful in gaining physician acceptance, which would adversely impact our ability to commercialize our product candidates, even if approved. Access will also depend on consumer acceptance and adoption of products that are commercialized.

In addition, responses by U.S. federal and state governments or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any of our product candidates, obtain or maintain regulatory approval, identify alternate regulatory pathways to market or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

We may not achieve our publicly announced milestones according to schedule, or at all.

From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. For example, we had previously announced that Phase 2a topline results of BPL-003 in the treatment of alcohol use disorder would be expected in 2024, but results are now expected to be announced in 2025. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results and the trading price of our common shares.

Because we have multiple programs and product candidates in our development pipeline, in addition to our continued business development activities, we may, and have in the past decided to, expend our limited resources and allocation of capital to pursue a

particular product candidate over other product candidates that may ultimately have been more profitable or for which there may have been a greater likelihood of success, which may adversely affect our future revenues.

Because we have limited financial resources and access to funding, we have to make decisions regarding the allocation of capital and resources across our businesses. For example, in March 2023, we announced that in conjunction with the Phase 2a study results of PCN-101 we would further evaluate the data and work with our subsidiary, Perception Neuroscience, to determine next steps for the program, including consideration of potential strategic partnership options. We face certain risks associated with these decisions. For example, we may forego or delay pursuit of certain product candidates or business opportunities that later may prove to have greater commercial potential than our current or future development programs and product candidates. In addition, our decisions concerning the allocation of research, collaboration, management and financial resources toward particular programs or product candidates may not lead to the development of viable commercial product candidates, and may divert resources, including personnel, away from more advantageous opportunities or from our other current programs. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product candidates and development programs could also prove not to be optimal and could cause us to miss valuable opportunities with no resulting benefit. If our assessment of the market potential of our product candidates or trends in the pharmaceutical or biotechnology industries proves to be inaccurate, our business, financial condition and results of operations could be materially adversely affected.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets and cash flows are and will continue to be influenced by movements in exchange rates of several currencies, particularly the U.S. dollar and the euro. Our reporting currency and our functional currency is primarily the U.S. dollar, but many of our operating expenses are paid in euro. We also regularly acquire services, consumables and materials in euro, and potential future revenue may be earned in euros. As a result, our business and the price of our common shares may be affected by fluctuations in foreign exchange rates between the U.S. dollar and the euro, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

We may use our existing cash, cash equivalents and short-term securities, to purchase digital currencies, including bitcoin, the price of which has been, and will likely continue to be, highly volatile.

We may use our cash, cash equivalents and short-term securities to purchase bitcoin. Bitcoin is a highly volatile asset that has traded below $40,000 per bitcoin and above $105,000 per bitcoin in the 12 months preceding the date of this annual report on Form 10-K. In addition, bitcoin does not pay interest or other returns and so the ability to generate a return on investment in bitcoin will largely depend on whether there is appreciation in the market price of bitcoin following our purchases of bitcoin.

Purchasing bitcoin exposes us to various risks, including the following:

- Bitcoin is a highly volatile asset, and fluctuations in the price of bitcoin may influence our financial results and the market price of our common shares;
- bitcoin and other digital assets are novel assets, and are subject to significant legal, commercial, regulatory and technical uncertainty;
- our historical financial statements do not reflect the potential variability in earnings that we may experience in the future relating to bitcoin holdings;
- due to the unregulated nature and lack of transparency surrounding the operations of many bitcoin trading venues, bitcoin trading venues may experience greater fraud, security failures or regulatory or operational problems than trading venues for more established asset classes, which may result in a loss of confidence in bitcoin trading venues and adversely affect the value of the bitcoin we own;
- the emergence or growth of other digital assets, including those with significant private or public sector backing, could have a negative impact on the price of bitcoin and adversely affect our business;
- bitcoin holdings are less liquid than our existing cash and cash equivalents and may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents;
- if we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our bitcoin, or if our private keys are lost or destroyed, or other similar circumstances or events occur, we may lose some or all of our bitcoin and our financial condition and results of operations could be materially adversely affected;
- we may face risks relating to the custody of bitcoin, including the loss or destruction of private keys required to access our bitcoin and cyberattacks or other data loss relating to our bitcoin; and

- regulatory change reclassifying bitcoin as a security could lead to our classification as an "investment company" under the Investment Company Act of 1940 and could adversely affect the market price of bitcoin and the market price of our common shares.

Risks Related to the Clinical Development, Regulatory Review and Approval of our Product Candidates.

Our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes. We cannot give any assurance that any of our product candidates will be successfully developed and/or receive regulatory approval, which is necessary before they can be commercialized.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive preclinical and clinical testing to evaluate the safety and efficacy of the product candidates in humans. Such testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials and providing general and administrative support for these operations. Some of our product candidates are in the preclinical stage, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support the planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the proposed clinical programs or if the outcome of preclinical studies will ultimately support the further development of the programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our clinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Moreover, the results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. The results of preclinical studies and clinical trials in one indication, or from preclinical studies or clinical trials that we did not lead, may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocol details. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA or other comparable foreign regulatory authorities to market and sell these product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, clinical trial design for some of our product candidates can be complex given their characteristics and issues associated with functional unblinding/disappointment effect. We also anticipate two independent, adequate, randomized, double blind and well-controlled pivotal trials in the patient populations will be necessary to support market approvals for all product candidates. Due to the substantial responses typically seen in the patient populations studied, placebo/control groups will be necessary to include to ensure that observed effects are not the result of spontaneous improvement, expectation bias, attention from health care professionals involved in the trial, regression to the mean, or other factors not related to the activity of the study drug.

Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to obtain approval and to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently have no products approved for sale and have not generated any revenue, and we may never be able to develop or successfully commercialize any of our product candidates. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA, the EMA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval.

All of our product candidates require additional development, management of preclinical, clinical and manufacturing activities and regulatory approval. In addition, we will need to obtain adequate manufacturing supply, build a commercial organization, commence marketing efforts and obtain reimbursement before they generate any significant revenue from commercial product sales, if ever. In

addition, while our new program selection criteria include prior evidence in humans and we believe the product candidates we have selected have the potential for a favorable safety profile based on third-party trials and studies, many of our product candidates are in early-stage research phases of development, and the risk of failure for these programs is high. In addition, some of the product candidates we are developing are derivatives of compounds that have undergone clinical trials that failed to meet their primary endpoints. For example, we are developing RL-007 for the treatment of CIAS but the same compound was tested in a Phase 2 trial as an analgesic to treat pain associated with diabetic polyneuropathy, and no efficacy was demonstrated. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue operations, which may result in dissolution, out-licensing the technology or pursuing an alternative strategy.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU has recently evolved. The CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025 and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations , or CROs, may impact our developments plans.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our operations and would have a material adverse impact on our platform or our business.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any of our planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers (with respect to certain of our clinical trials) to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("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 identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB or ethics committees' approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA, or amendment, investigational device exemption ("IDE") or supplement, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments in trials for other product candidates with the same targets or related modalities as our product candidates conducted by competitors that raise regulatory or safety concerns about risk to patients of the treatment, or if the FDA or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulties in securing access to materials for the comparator arm of certain of our clinical trials;

- delays in identifying, recruiting and enrolling suitable patients to participate in clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulties in finding a sufficient number of trial sites, or trial sites deviating from trial protocol or dropping out of a trial;
- difficulty collaborating with patient groups and investigators;
- failure by CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's GCPs or regulatory guidelines in other countries, including deficiencies in the manufacturing process, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- occurrence of AEs undesirable side effects or other unexpected characteristics associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of any product candidates that we may identify and pursue being greater than we anticipate;
- clinical trials of any product candidates that we may identify and pursue producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failures by our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of product candidates that we may identify for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct additional preclinical studies or clinical trials to bridge data obtained from the modified product candidates to data obtained from preclinical and clinical research conducted using earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board or by the FDA, or other comparable foreign regulatory authorities, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down the product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IDE, IND, CTA or equivalent application, as applicable, will result in the FDA, or comparable foreign regulatory authority allowing clinical trials to begin in a timely manner, if at all. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our current product candidates and future product candidates may be subject to controlled substance laws and regulations in the territories where the product will be marketed, such as the United States and Europe, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

Some of our product candidates are regulated by the DEA as "Controlled Substances" or scheduled substances, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act ("CSA"). The DEA regulates compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted

medical use" in the United States, lack accepted safety for use under medical supervision and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. Commercial marketing in the United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require the DEA to conduct notice and comment rule making, including issuing an interim final rule. Such action will be subject to public comment and requests for hearing, which could affect the scheduling of these substances. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), at the federal level, such substances would also require scheduling determinations under state laws and regulations.

If approved by the FDA, and if any of our product candidates is listed by the DEA as a Schedule II, III, IV or V controlled substance, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will continue to be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our product candidates in the United States. Furthermore, the FDA, DEA or any foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of our product candidates and any future product candidates containing controlled substances. In addition, product candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- *DEA registration and inspection of facilities*. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

- *State-controlled substances laws*. Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval, and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

- *Clinical trials*. Our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our product candidates and to obtain the product from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import.

- *Importation*. If our product candidates are approved and classified as a Schedule II, III or IV substance, an importer can import them for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration. If our product candidates are approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If our product candidates are listed as a Schedule II substance, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if neither our product candidates nor our drug substances could be imported, the product candidates would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.
- *Manufacture in the United States*. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the active ingredient in our product candidates may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.
- *Distribution in the United States*. If our product candidates are scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our product candidates and any future therapeutic candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our product candidates more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If our product candidates are a Schedule II drug, participants in our supply chain may have to maintain enhanced security with alarms and monitoring systems and they may be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. In addition, our product candidates will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial updates. Furthermore, state and federal enforcement actions, regulatory requirements and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

The EU legislation does not establish different classes of narcotic or psychotropic substances. However, the UN Conventions codify internationally applicable control measures to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The individual EU member states are all signatories to these UN Conventions. All signatories have a dual obligation to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence.

The UN Conventions require signatories to require all persons manufacturing, trading (including exporting and importing) or distributing controlled substances to obtain a license from the relevant authority. Each individual export or import of a controlled substance must also be subject to an authorization. The obligations provided in the UN Conventions and additional requirements are implemented at national level and requirements may vary from one member state to another. In order to develop and commercialize our products in the EU, we need to comply with the national requirements related to controlled substances which is costly and may affect our development plans in the EU.

Our product candidates contain psychedelic substances, the use of which may generate public controversy. Adverse publicity or public perception regarding our current or future product candidates may negatively influence the success of these therapies.

Our product candidates contain psychedelic substances that may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our current product candidates and any future product candidates we may develop. Opponents of these compounds may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products, if approved. Adverse publicity from misuse of psychedelics, whether or not tied to our product candidates, may adversely affect the commercial success or market penetration achievable by our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our product candidates or any future therapeutic candidates.

If our product candidates or any future therapeutic candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of the safety and quality of our product candidates. We may face limited adoption if third-party therapy sites, therapists or patients are unwilling to try such a novel treatment given that some of our product candidates are from substances that might be controversial, overlooked or underused. There has been a history of negative media coverage regarding psychedelic substances, including compounds in many of our product candidates, which may affect the public's perception of our product candidates. In addition, compounds in most of our product candidates may elicit intense psychological experiences, and this could deter patients from choosing this course of treatment, if our product candidates were approved. Our business could be adversely affected if we were subject to negative publicity or if any of our product candidates, if approved, or any similar product candidates distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of any of our product candidates, if approved or any similar products distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into depression and other mental health disorders, such as substance use disorder and anxiety, on which we focus our research efforts, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates or any future product candidates.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the potential commercialization of our product candidates.

Any product candidates we may develop and the activities associated with their development and potential commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, and other comparable foreign regulatory authorities. Failure to obtain marketing authorization for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction.

We expect to rely on assistance from third-party CROs or regulatory consultants to assist us in filing and supporting the applications necessary to gain marketing authorizations. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, or with respect to biological products in the U.S., the product candidate's safety, purity and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, if approved.

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing authorization policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval, or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Research and development of drugs targeting CNS is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others, which may reduce the likelihood our product candidates are ultimately approved and therefore may have a material adverse effect on our business and operating results.

Discovery and development of new drug candidates designed to target CNS disorders are particularly difficult and time-consuming, evidenced by the higher failure rate for new drugs for CNS disorders compared with most other areas of drug discovery. For example, in 2019, both Rapastinel and SAGE-217, two third-party developed drug candidates designed to target MDD failed to meet their primary endpoints in Phase 3 clinical trials. The New Drug Application, or NDA, submitted by Alkermes for ALKS 5461, another drug candidate under development for MDD, was not approved by the FDA in 2019 because the FDA reportedly required additional clinical data to provide substantial evidence of effectiveness beyond the Phase 3 clinical trials that had already been conducted. Any such setbacks in our clinical development could decrease the likelihood our product candidates are approved and may ultimately have a material adverse effect on our business and operating results. In addition, our later-stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, particularly as it regards managing placebo effects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying trial participants to participate in clinical studies is critical to our success. The timing of our clinical trials depends, among other things, on the speed at which we can recruit trial participants to participate in testing our product candidates and our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. Delays in enrollment and withdrawals from the trial may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of our product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidate development, delays in testing the effectiveness of these product candidates, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. Patient and subject enrollment is affected by factors including:

- the size and nature of a patient population;
- the patient eligibility criteria defined in the applicable clinical trial protocols, which may limit the patient populations eligible for clinical trials to a greater extent than competing clinical trials for the same indication;
- the size of the study population required for analysis of the trial's primary endpoints;
- the severity of the disorder under investigation;
- the proximity of patients to a trial site;
- the inclusion and exclusion criteria for the trial in question;
- the design of the trial protocol;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the approval or concurrent enrollment of clinical trials involving competing product candidates currently under development or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- the availability and efficacy of approved medications or product candidates for the disorder or condition under investigation;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available product candidates and product candidates;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

Additionally, our or our collaborators' ability to successfully initiate, enroll and conduct a clinical trial outside the United States is subject to numerous additional risks, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- differing standards for the conduct of clinical trials;
- differing standards of care for patients with a particular disorder;
- an inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

If we have difficulty enrolling sufficient numbers of patients to conduct clinical trials as planned, we may need to delay or terminate clinical trials, either of which would have an adverse effect on our business.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, cause us to

abandon a product candidate, limit their commercial potential, if approved, or result in other significant negative consequences that could severely harm our business, prospects, financial condition and results of operations.

As is the case with pharmaceuticals generally, it is likely that there may be unexpected or undesirable side effects, AEs and other risks associated with the use of our product candidates. For instance, there have been fatalities associated with the use of ibogaine including in third-party clinical trials, potentially due in part to the inappropriate management of cardiovascular risks, inadequate cardiac monitoring and drug product of unknown purity and concentration. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by these product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, or other comparable foreign regulatory authorities. The side effects related to the product candidate could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify or terminate our study plans based on findings in our preclinical studies or clinical trials. Many product candidates that initially show promise in early-stage testing may later be found to cause side effects that prevent further development. As we work to advance existing product candidates and to identify new product candidates, we cannot be certain that later testing or trials of product candidates that initially showed promise in early testing will not be found to cause similar or different unacceptable side effects that prevent their further development.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other AEs that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

Additionally, adverse developments in clinical trials of pharmaceutical, biopharmaceutical or biotechnology products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such AEs occur, our clinical trials could be suspended or terminated. If we are unable to demonstrate that any AEs were caused by the administration process or related procedures, the FDA or other regulatory authorities could order us to cease further development of, or deny approval of, a product candidate for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition, results of operations and prospects significantly.

Additionally, if any of our product candidates receive marketing authorization, the FDA or other regulatory authorities could impose contraindications or a boxed warning in the labeling of the product. For any of our drug product candidates receiving marketing authorization, the FDA or other regulatory authorities could require us to adopt a REMS or similar risk management measures and could apply elements to assure safe use to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates if approved, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Deal Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required by the FDA or other regulatory authorities to implement a REMS or similar risk management measures;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and may harm our business, financial condition, results of operations and prospects significantly.

Even if any of our current or future product candidates receive regulatory approval, any such product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our current or future product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians may be reluctant to take their patients off their current medications and switch their treatment regimen. Further, patients often acclimate to the treatment regime that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. In addition, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product as demonstrated in pivotal clinical trials;
- the potential and perceived advantages of the product compared to competitive and alternative products;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of dosing and administration compared to alternative treatments, including the need to have products administered in clinical settings, rather than the home, for patients who are prescribed the products;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning these products or competing products and treatments;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any of our products is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidates we develop do not achieve an adequate level of acceptance, they may not generate significant product revenue, and we may not become profitable.

For any of our current or future product candidates that obtains regulatory approval, any failure to achieve market acceptance or commercial success would adversely affect our business prospects. In addition, for any approved product, any negative perception of such product once commercialized, or of a similar product developed by a competitor, may adversely affect our reputation in the marketplace or among industry participants and our business prospects.

We currently, and may in the future continue to, conduct clinical trials for product candidates outside the United States, and the FDA, the EMA and comparable foreign regulatory authorities may not accept data from such trials.

We currently, and may in the future continue to, conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, the EMA, the MHRA or any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the applicable clinical trial was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA, the MHRA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, the EMA, the MHRA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

If we are unable to obtain regulatory approval in one or more jurisdictions for any product candidates that we may identify and develop, our business will be substantially harmed.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable foreign regulatory authorities is lengthy and unpredictable, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of preclinical or clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any of our product candidates, and it is possible that our current product candidates and any other product candidates that we may seek to develop in the future will not ever obtain regulatory approval. We cannot be certain that any of our product candidates will receive regulatory approval or be successfully commercialized, even if they receive regulatory approval.

Obtaining marketing approval is an extensive, lengthy, expensive and inherently uncertain process, and regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including but not limited to:

- the inability to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that the applicable product candidate is safe and effective as a treatment for our targeted indications or otherwise meets the applicable regulatory standards for approval;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design, endpoints or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety or efficacy in the full population for which we seek approval;
- the FDA, the EMA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates that we may identify and pursue may not be sufficient to support the submission of an NDA or other submission for regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, the EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, the EMA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, or comparable foreign regulatory authorities may change in a manner that renders the clinical trial design or data insufficient for approval.

The approval process, as well as the unpredictability of the results of clinical trials and evolving regulatory requirements, may result in our failure to obtain regulatory approval to market product candidates that we may pursue in the United States or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

Furthermore, approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our clinical trials or from clinical trials conducted by companies that we invest in, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from these trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and top-line, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Certain of the product candidates we are developing are complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

The manufacturing processes our CMOs use to produce our product candidates are complex, and materials are challenging to source. Several factors could cause production interruptions, including an inability to develop efficient manufacturing processes, equipment malfunctions, facility contamination, raw material shortages or contamination, supply chain disruptions, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers, including acquisition of the supplier by a third-party or declaration of bankruptcy.

Our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA, or other applicable standards or specifications with consistent and acceptable production yields and costs.

Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We or our CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our or our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our or our CMOs' manufacturing process could restrict our or their ability to meet potential future market demand for products, if approved.

We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to drug product candidates granted breakthrough therapy or fast track designation by the FDA or similar EMA expedited pathways.

We intend to evaluate and continue ongoing discussions with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our product candidates in the future, although we cannot be certain that our product candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations. Potential expedited development pathways that we could pursue include breakthrough therapy and fast track designation.

Drug candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track-designated product has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may also designate a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track designation features, as well as more intensive FDA interaction and guidance.

We cannot assure you that the FDA will grant breakthrough or fast track designation for our product candidates, even if requested. Breakthrough therapy designation and fast track designation do not change the standards for product approval, and there is no assurance that even if we receive such designation, it will result in expedited review or approval or that any approved indication will not be narrower than the indication covered by the breakthrough therapy designation or fast track designation. Therefore, even if we receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

We may seek EMA PRIME (PRIority MEdicines) designation or other designations, schemes or tools for one or more of our product candidates, which we may not receive. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.

For any approved product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates, which may adversely impact our financial condition and results of operations.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, and other comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP and similar regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and similar requirements and adherence to commitments made in any NDA or MAA or equivalent application. We and our CMOs are also subject to numerous other requirements pertaining to the registration of our and their manufacturing facilities and the listing of our product and product candidates with the FDA and other comparable foreign regulatory authorities, including with respect to manufacturing, production and quality control. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance. Additionally, under FDA regulations, certain of our product candidates that we expect to be regulated as combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulation applicable to medical devices, which may delay or prevent approval, or prohibit or suspend marketing of our products in certain jurisdictions. Similar requirements may apply in foreign jurisdictions and for instance, in the EU, where medical devices are highly regulated.

Any regulatory approvals that we may receive for our product candidates may contain requirements for potentially costly post-marketing testing, such as additional clinical trials and surveillance to monitor the safety and efficacy of a drug product. We are required to report certain adverse reactions and production problems, if any, to the FDA, and other comparable foreign regulatory authorities. Any new legislation addressing drug or medical safety issues could result in delays in product development or commercialization or increased costs to assure compliance.

The FDA and other agencies, including the U.S. Department of Justice, and for certain products, the Federal Trade Commission, closely regulate and monitor the post-approval marketing, labeling, advertising and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved label. We are, and will be, required to comply with requirements concerning advertising and promotion for our product candidates, if approved. For example, promotional communications with respect to prescription drugs and medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's label or labeling. Accordingly, we may not promote our products for indications or uses for which they do not have approval.

The holder of an approved NDA, MAA or equivalent marketing authorization must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. Delays in obtaining required approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our or our future growth. Failure to submit a new or supplemental application and to obtain approval for certain changes prior to marketing the modified product may require a recall or to stop selling or distributing the marketed product as modified and may lead to significant enforcement actions.

We could also be required to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as AEs 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, such 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 or untitled letters;
- impose civil or criminal penalties;
- suspend, withdraw or modify regulatory approvals;

- suspend or modify any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;
- impose restrictions on our operations, including closing our programs' or our or their CMOs' facilities;
- seize or detain products, refuse to permit the import or export of products; or
- require a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the results of the 2024 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration may issue executive orders or take other actions that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. The policies and priorities of a new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA and other regulatory agencies permit the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees, corporate integrity agreements or imposed permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

Risks Related to Commercialization

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to market and sell our product candidates, if and when they are approved. We may also elect to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to selected product candidates, indications or geographic territories, including territories outside the United States, although there is no guarantee we will be able to enter into these arrangements even if the intent is to do so.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and/or distribution services, the profitability of any product revenue we receive may be lower than if we were to market, sell, provide commercial support for and/or provide distribution services for any products developed by us. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us or them. We may 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 products effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

The availability of adequate third-party coverage and reimbursement for newly approved drugs is uncertain, and failure to obtain adequate coverage and reimbursement from third-party payers could impede our ability to market any future products we may develop and could limit our ability to generate revenue.

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved drugs. The commercial success of our future products in both domestic and international markets depends on whether such third-party coverage and reimbursement is available for our product candidates. Governmental payers, health maintenance organization, managed care, pharmacy benefit and other third-party payers are increasingly attempting to manage their healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate reimbursement for our product candidates, which is essential for most patients to be able to afford treatments. These payers may not view our future products as cost-effective, and coverage and reimbursement may not be available to our customers, may not be sufficient to allow our future products to be marketed on a competitive basis and will impact our ability to successfully commercialize our product candidates. Government authorities and third-party payers are exerting increasing influence and control on costs, known as cost containment, on their decisions regarding the use of, and coverage and reimbursement levels for, particular medications and treatments. In particular, third-party payers may limit the covered indications. This trend in cost-control initiatives in the United States and other countries could cause us to decrease the price we might establish for products, and monitor and control company profits, which could result in lower than anticipated product revenues. If the prices for our drug candidates decrease or if governmental and other third-party payers do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, financial condition and results of operations could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to government or other third-party payers, certain healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse regulation by governments and regulators where we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- Federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements to obtain payment from the federal government. In addition, 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 federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies 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 and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Even if we are successful in defending ourselves or asserting our rights, the existence of these actions may adversely affect market prices of our common shares.

The production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions and therefore we may not be successful in commercializing our product candidates in such jurisdictions, which will adversely affect our business, financial condition and results of operations.

Our product candidates contain controlled substances, including psychedelic substances, which are subject to strict legal requirements in certain jurisdictions where we will produce and intend to sell our products, if approved. Certain jurisdictions may not allow the use or production of the substances included in our product candidates, nor provide any possibilities for an exemption or regulatory approval that could allow for the lawful use or production of such substances. In addition, these jurisdictions may prohibit any form of contributing to the production or use of these drug candidates and may also directly or indirectly prohibit the receipt of any benefits following from the production and sale of these substances. Under certain circumstances, this may have consequences for the legality of the purchase of our shares or receipt of dividends in or from foreign jurisdictions.

If certain foreign authorities consider it illegal to invest in our company, this will negatively affect the possibility to commercialize and generate revenue in the country of interest. Any investigations of authorities against foreign investors could generate negative publicity. We cannot predict the likelihood of foreign authorities to take such a point of view or take any actions against investors in certain jurisdictions.

Actual or perceived failure to comply with health and data protection laws, regulations, and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity or reputational impacts, each of which could have a materially adverse effect on our operating results, financial condition, and business.

In connection with running our business, we receive, store, use and otherwise process information that relates to individuals and/or may constitute "personal data," "personal information," "individually identifiable health information," "protected health information," or similar terms under applicable data protection laws (collectively, "Personal Information"), including from and about actual or prospective clinical trial participants, patients, employees, and business contacts. We also depend on third party vendors in relation to the operation of our business, a number of which process Personal Information on our behalf.

We, our vendors, and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder (collectively, "HIPAA"), imposes, among other requirements, certain standards relating to privacy, security, and breach reporting for "protected health information." HIPAA is applicable to healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting protected health information. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and therefore are not directly regulated under HIPAA, we may obtain protected health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, and therefore we may be considered a "business associate." Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. Department of Health and Human Services.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, consumer health data protection laws in Washington and Nevada impose significant obligations on entities that collect "consumer health data," and a failure to comply with these laws may result in enforcement actions or litigation. We may also be subject to other state and federal laws governing the privacy, processing, and protection of Personal Information. For example, California enacted the California Consumer Privacy Act, which requires covered businesses that process the Personal Information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their Personal Information; (ii) receive and respond to requests from California residents to access, delete, and correct their Personal Information, or to opt out of certain disclosures of their Personal Information; and (iii) enter into specific contractual provisions with service providers that process California resident Personal Information on the business's behalf. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States

In Europe and the UK, we are subject to the European Union General Data Protection Regulation 2016/679 and applicable national supplementing laws ("EU GDPR") and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 ("UK GDPR" and together with the EU GDPR, the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health data and other sensitive data, obtaining consent of the individuals to whom the personal data relate, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, taking certain measures when engaging third-party processors and introducing a principal of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR, and subject to additional compliance obligations and to local law derogations. We may be subject to diverging requirements under EU member state laws and UK law, such as whether consent can be used as the legal basis for processing and the roles, responsibilities and liabilities as between clinical trial sites and sponsors. As these laws develop, we may need to make operational changes to adapt to these diverging rules, which could increase our costs and adversely affect our business.

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million/GBP 17.5 million or 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. Since we are subject to the supervision of relevant data protection authorities under both the EU GDPR and the UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA or UK, including from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission or UK government does not recognize as having "adequate" data protection laws. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, in particular in relation to transfers to the United States. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF") rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. On October

12, 2023, the UK Extension to the DPF also came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

The applicable laws, rules and regulations relating to privacy and data security are in some cases relatively new and the interpretation and application of these laws are uncertain. Any failure or perceived failure by us to comply with data privacy laws, rules, regulations, industry standards and other requirements could result in proceedings or actions against us by individuals, consumer rights groups, government agencies, or others. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our business. Further, these proceedings and any subsequent adverse outcomes may subject us to significant negative publicity and an erosion of trust. Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. If any of these events were to occur, our business, results of operations, and financial condition could be materially adversely affected.

In addition, we use AI, ML, and automated decision-making technologies (collectively, "AI Technologies") in our business. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs 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 certain branded prescription drugs.

Payment methodologies may be subject to changes in healthcare legislation and regulatory challenges. For example, in order for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price ("ASP") plus 6 percent to ASP minus 22.5 percent on specified covered outpatient drugs but did so without issuing a formal notice of proposed rulemaking, which was subsequently challenged in court. In June 2022, the U.S. Supreme Court held that although the Department of Health and Human Services ("HHS") has authority to set reimbursement rates based on average price and discretion to "adjust" the price up or down, HHS may not vary the reimbursement rates by hospital group unless it conducts a survey of hospitals' acquisition costs. Accordingly, the U.S. Supreme Court held that HHS's changes

to the 2018 and 2019 reimbursement rates for 340B hospitals were unlawful. Based on the foregoing, CMS issued a final rule, effective January 1, 2023, pursuant to which CMS pays 340B hospitals under Medicare Part B for certain outpatient drugs at the drug's ASP, plus 6%, the same rate used for non-340B hospitals. It is unclear how future changes to the payment methodology may affect pharmaceutical manufacturers and hospitals who purchase their products now and in the future.

There have been a number of significant changes to the ACA and its implementation, as well as judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, resulted in aggregate reductions of Medicare payments to providers, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that the other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any.

In some countries, including member states of the EU, the pricing of prescription medicinal products is subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. We cannot be sure that such prices and reimbursement will be acceptable to us. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before we do or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The pharmaceutical industry is highly competitive, with new approaches and technologies regularly emerging. We expect to face competition across our current programs and with any future programs we may seek to develop and/or commercialize from major pharmaceutical, biotechnology, specialty pharmaceutical and generic pharmaceutical companies among others. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. In addition, programs that we currently believe to be complementary may eventually become competitors.

If any of our competitors receives FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

We face competition across our programs in depression, including from Axsome Therapeutics, GH Research, The Janssen Pharmaceutical Companies of Johnson & Johnson, Cybin, Neumora Therapeutics, Alto Neuroscience, Neurocrine Biosciences, as well as COMPASS, in which we hold an equity stake; CIAS, including from Neurocrine Biosciences and Alto Neuroscience and; SAD, including from VistaGen Therapeutics, Engrail Therapeutics, Neuphoria Therapeutics, MindMed, Cybin, Intracellular-Therapies and Lykos Therapeutics; as well as in other therapeutic areas and indications.

Many of our current or potential competitors, either alone or with their strategic partners, may have or develop in the future:

- greater financial, technical, and human resources than we have at every stage of the discovery, development, manufacture, and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing, and selling drug products;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disorder indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors may also obtain FDA, or other comparable foreign regulatory approval for their products more rapidly than we may obtain approval for ours or may obtain orphan product exclusivity from the FDA or other comparable foreign authorities for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our

product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our programs' patents relating to our competitors' products, and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Our ability to successfully identify patients and acquire a significant market share will be necessary for us to achieve profitability and growth.

We focus research and product development on treatments for mental health disorders, including depression, substance use disorder, anxiety and other neurological indications. Our projections of both the number of individuals who are affected by our target disorder indications and have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of patients may turn out to be lower than expected. The effort to identify patients with these mental health disorders we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for our product candidates that we may identify may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations may be small, we may never achieve profitability.

Risks Related to Reliance on Third Parties

We are currently party to and may seek to enter into additional collaborations, licenses and other similar arrangements and may not be successful in maintaining existing arrangements or entering into new ones, and even if we are, we may not realize the benefits of such relationships.

We are currently party to license and collaboration agreements with a number of universities and pharmaceutical companies, and we expect to enter into additional agreements as part of our business strategy. We anticipate relying upon strategic collaborations for marketing and commercializing our existing product candidates, if approved, and we may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. The success of our current and any future collaboration arrangements may depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, such as:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our programs' intellectual property rights or may use our programs' intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us or our programs to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, which may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;

- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and research and development programs with the marketing and research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

Additionally, we may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our research and development efforts and potential to generate revenue may be limited. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of research and preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If we need to enter into alternative arrangements, it could delay product development activities.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each trial is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each clinical trial is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other comparable foreign authorities requires compliance with requirements, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA and other comparable foreign authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in their clinical trials may be deemed unreliable, and the FDA and other comparable foreign authorities may require additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA or other comparable foreign authorities will determine that any of our clinical trials have complied with GCPs. We are also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under the agreements with such contractors, we cannot control whether or not such contractors devote sufficient time, skill and resources to their ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug or medical device development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials, and we expect this to continue upon approval, if any, of our current or future product candidates. If third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed.

We currently administer certain of our product candidates in our clinical trials through qualified third-party therapists working at third-party clinical trial sites. However, there are currently not enough trained therapists to carry out our therapies at a commercial scale, and our efforts to facilitate training and certification programs for therapists may be unsuccessful.

While we currently provide training to the therapists and expect to continue providing trainings in the future (either directly or indirectly through third-party providers), we do not currently employ the therapists who deliver our therapies to patients and do not intend to do so in the future. We generally rely on qualified and certified third-party therapy sites to manage the therapists and monitor the administration of our therapies and ensure that the administration process of our therapies comply with our established protocols. If any of our current or any future product candidates are approved for commercialization, third-party therapy sites may demand substantial financial resources from us to recruit and retain a team of qualified therapists to administer such products. If the third-party therapy sites fail to recruit, train and retain a sufficient number of therapists, our ability to offer and administer our therapies will be greatly harmed, which may in turn reduce the market acceptance rate of our therapies. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed. Additionally, if the third-party therapy sites do not properly manage and supervise the therapists, there is a risk that therapists may deviate from our training protocols, fail to follow the guidelines we have established, or abuse patients during therapeutic administration sessions. The therapists might also administer unauthorized therapies to patients using illegal drug compounds in "underground" clinics. Such illegal activities would put the patients at risk and subject us to potential liabilities, litigation, regulatory proceedings and reputational harm. If this were to occur, we may face serious setbacks for our commercialization process and our financial condition and results of operations would be materially harmed.

Our use of third parties to manufacture and develop our product candidates for preclinical studies and clinical trials may increase the risk that we will not have sufficient quantities of our product candidates or if approved, our products, or necessary quantities of such materials on time or at an acceptable cost, and that a competitor or other third party will discover our trade secrets or such trade secrets will be misappropriated or disclosed.

We generally rely, and expect to continue to rely, on third-party manufacturers to produce our product candidates or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if any product candidates receive marketing authorization and approval. Although we generally do not begin a clinical trial unless we believe they have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay the clinical development and potential regulatory authorization of our product candidates, which could harm our business and results of operations.

We may be unable to identify and appropriately qualify third-party manufacturers or establish agreements with third-party manufacturers or do so on acceptable terms. Even if they are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for sourcing of raw materials, components, and such other goods as may be required for execution of its manufacturing processes and the oversight by the third-party of its suppliers;
- reliance on the third-party for regulatory compliance and quality assurance for the manufacturing activities each performs;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of proprietary information, including trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Furthermore, we and our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. The facilities used by our contract manufacturers to manufacture our drug or medical device product candidates are subject to review by the FDA, MHRA and other comparable foreign authorities pursuant to inspections that will be conducted after we submit an NDA, or other marketing application to such regulatory authorities. We do not control the manufacturing process of, and are to some extent dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMP requirements for manufacture of drug and device products or similar requirements outside the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, MHRA or other comparable foreign authorities, we will not be able to secure or maintain regulatory authorization for our product candidates manufactured at these manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, or another comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if any agency withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory authorization for or market our product candidates, if approved.

Our product candidates may compete with other product candidates and marketed products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or commercialization. Our current and anticipated future dependence upon others for the manufacturing of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

If the contract manufacturing facilities on which we rely do not continue to meet regulatory requirements or are unable to meet our supply demands, our business will be harmed.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for our product candidates, are subject to extensive regulation. Components of a finished drug or product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We and our CMOs must supply all necessary documentation, as applicable, in support of a marketing application, such as an NDA or MAA, on a timely basis and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must successfully complete a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with the regulatory requirements. If these facilities do not successfully complete a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third-party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified. For drug products, an NDA supplement or MAA variation, or equivalent foreign regulatory filing is also required, which could result in further delay. Similarly, for any product regulated as a medical device or drug-device combination product, a new marketing application or supplement may be required. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, and we could lose potential revenue.

We have no sales, distribution, or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third parties to market and sell our future products, if approved, we may be unable to generate any revenues.

Given our stage of development, we have no sales, distribution, or marketing experience. To successfully commercialize any products that may result from our development programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into strategic alliances with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future strategic collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our existing product candidates or any other product candidates that we may identify, or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our existing product candidates and any other product candidates that we may pursue may be impaired.

As is the case with other pharmaceutical and biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad and in-licensing intellectual property related to our existing product candidates, our various proprietary technologies and any other product candidates or technologies that we may identify.

Obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such 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. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, we may experience difficulties in enforcing the intellectual property rights in output generated by generative AI Technologies. The United States Copyright Office has previously denied copyright protection for content generated by AI Technologies, and the United States Patent and Trademark Office has similarly stated that an AI tool cannot be an “inventor” of a patent, rendering it impossible to obtain patent protection for inventions created solely by AI Technologies. The Supreme Court of the United Kingdom has reached a similar conclusion, stating that AI systems cannot be named as an “inventor” for UK patent law purposes.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of much litigation. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In some instances, we submit patent applications directly with the USPTO as provisional patent applications. However, U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of the provisional application filing date. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Any pending and future patent applications that we own or in-license may not result in patents being issued

that protect our product candidates or technology, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications that we own or license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative product candidates in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. For example, the United States federal government retains such rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. The research resulting in certain of our in-licensed patent rights and technology was funded in part by a governmental authority, for example, the U.S. government and the Japanese government. As a result, such governmental authority may have certain rights, including march-in rights, to such patent rights and technology, under the Bayh-Dole Act or similar laws in other jurisdictions and our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights or by any third-party of its reserved rights could harm our competitive position, business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on their licensors.

We currently are reliant upon licenses of certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our proprietary technology, including technology related to our product candidates. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our competitive position, business, financial condition, results of operations and prospects significantly.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable

intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize product candidates, we may be unable to achieve or maintain profitability. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property rights that are subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to various agreements that we depend on to develop our product candidates and various proprietary technologies, and our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. For example, under certain of our license agreements, we are subject to certain diligence obligations, including to use commercially reasonable efforts to develop and commercialize product candidates covered by the licensed intellectual property rights and to maintain the licensed intellectual property rights, each of which could result in the termination of the relevant license agreements in the event we fail to comply.

Despite our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, certain provisions in our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Our competitors in both the United

States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to issued patents, and a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. In addition, many companies in the biotechnology and pharmaceutical industries have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our existing product candidates and any other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

There may be other third-party patents or patent applications with claims to composition of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our existing or future product candidates. Further, we may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property rights.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, prospects, financial condition and results of operations.

Patent terms may be inadequate to protect our competitive position on product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Amendments and in foreign countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments allow a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be

extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, such as the Supplementary Protection Certificates in Europe. In particular, a maximum of five and a half years of supplementary protection can be achieved in Europe for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection.

Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially, which would have a material adverse effect on our business, financial condition and results of operations.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If or when one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any ANDA filed with the FDA to obtain permission to sell a generic version of such product candidate.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and we cannot be certain 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 and other confidential proprietary technology, or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know, whether the steps we have taken to protect our intellectual property will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic institutions to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets and proprietary information, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of such information may be greatly reduced and our competitive position, business, financial condition, results of operations and prospects would be harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and

trade names or may be forced to stop using those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and our issued patents covering our product candidates could be found invalid or unenforceable if challenged in courts or patent offices.

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. If we were to initiate legal proceedings against a third-party to enforce a patent covering one or more of our product candidates, the defendant could allege that we infringe their patents, assert counterclaims that the patent covering our product candidate is invalid and/or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or

developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Further, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue clinical trials, continue research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring product candidates to market. 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. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

Our agreements with employees and contractors and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements assigning such intellectual property to us, we may not obtain these agreements in all circumstances, the assignment of intellectual property rights may not be self-executing and individuals with whom we have entered into these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. 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.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or other third parties. We may also become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. We may also 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. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of our owned and licensed patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. However, we cannot guarantee that our licensors have similar systems and procedures in place to pay such fees. In addition, the USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many 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 non-compliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. 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, financial condition, results of operations, and prospects.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on our 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 may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, 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, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, in EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be

adversely affected by unforeseen changes in foreign intellectual property laws. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, geopolitical developments around the world could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Additionally, the United States and foreign government actions related to conflict in the Middle East, including the ongoing conflict between Hamas and Israel, may limit or prevent filing, prosecution, and maintenance of patent applications in Israel. Government actions may also prevent maintenance of issued patents in Israel. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Israel. If such an event were to occur, it could have a material adverse effect on our business.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our programs' ability to protect their products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to a patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in licensed patent applications and the enforcement or defense of our owned or in licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. For example, 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Recent decisions, including by the U.S. Court of Appeals for the Federal Circuit, raise questions regarding the award of Patent Term Adjustment ("PTA") for patents in families where related patents have issued without PTA. Therefore, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted.

Further, in Europe, the new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Risks Related to Our Business and Industry

Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, our directors, as well as the other members of our scientific and clinical teams, including Christian Angermayer, our co-founder and chair of our supervisory board of directors and Srinivas Rao, our co-founder and Chief Executive Officer. The loss of the services of any of our executive officers and other key personnel, and our inability to find suitable replacements could result in delays in product development and our financial condition and results of operations could be materially adversely affected. In addition, because certain of our key personnel provide a centralized source of support across multiple of our programs, the loss of any of these key personnel could negatively affect the operations of the affected programs, and our financial condition and results of operations could be materially adversely affected.

Furthermore, each of our executive officers may terminate their employment with us at any time, subject to notice period requirements. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We may need to periodically realign our organization and may experience difficulties in managing either potential growth or reductions in force, which could disrupt our operations.

As we mature, we may need to realign our full-time employee base. This can include expansion or reductions in force, depending on our needs. Our management has diverted, and may need to continue, to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time toward managing these realignment activities. We may not be able to effectively manage a potential realignment of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. For example, in 2024 we identified redundancies among certain positions, which resulted in a reduction in force of approximately 10% of our global workforce. If our management is unable to effectively manage our internal realignment, our expenses may increase more than expected in the event of an expansion, our ability to generate and/or grow revenues 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 realignment of our employee base.

Because we are developing multiple product candidates and are pursuing a variety of target indications and treatment modalities, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or other potential product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and personnel resources, we may forgo or delay pursuit of opportunities with potential target indications or product candidates that later prove to have greater commercial potential than our current and planned product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be required to relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain development and commercialization rights to such future product candidates.

Additionally, we may pursue additional in-licenses, investments in or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify investments or programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any of our product candidates.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- an adverse impact on the market prices of our common shares; and
- the inability to commercialize our product candidates.

Although our programs maintain product liability insurance, including coverage for clinical trials that we sponsor, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials and if our programs successfully commercialize any product candidates.

The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our programs increase in size. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We could experience difficulty enforcing our contracts.

Due to the nature of our business and the fact that our contracts involve certain substances whose usage is not legal under U.S. federal law and in certain other jurisdictions, we may face difficulties in enforcing our contracts in U.S. federal and state courts. The inability to enforce any of our contracts could have a material adverse effect on our business, prospects, financial condition and results of operations.
In order to manage our contracts with contractors, we ensure that such contractors are appropriately licensed at the state and federal level in the United States and at the appropriate level in other jurisdictions. Were such contractors to operate outside the terms of these licenses, we may experience an adverse effect on our business, including the pace of development of our product candidates and any future therapeutic candidates.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the significant number of mental health disorders our therapeutic candidates are being developed to treat, and we intend to utilize appropriate social media in connection

with our commercialization efforts if and when our product candidates receive regulatory approval. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations. In addition, we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors as well as the employees, independent contractors, consultants, commercial partners and vendors of our programs. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities. If we obtain FDA or foreign approval of our product candidates and begin commercializing those products in the United States or abroad, as applicable, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third parties, 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. 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, including the imposition of significant fines or other sanctions.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their businesses. If we were to face any employment or harassment-related claims, our business could be negatively affected.

If we or our third-party manufacturers or suppliers fail to comply with environmental, health and safety laws and regulations, we or our third-party manufacturers or suppliers could become subject to fines or penalties or other sanctions or incur costs that could harm our business.

We and our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the generation, handling, use, storage, treatment, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury resulting from these materials or waste products. In the event of such contamination or injury, we could be held strictly, jointly and severally liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

Environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We and our third-party manufacturers and suppliers may incur substantial costs in order to comply with current or future environmental, health and

safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure by us or our third-party manufacturers and suppliers to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Cyberattacks, data security incidents, or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption, legal liability, damage to our reputation, and significant disruption of our business operations which could materially affect our operating results, financial condition, and business.

We, our programs, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants rely on information technology, or IT, systems and networks (collectively, "IT Systems") to process, transmit and store electronic information, including but not limited to intellectual property, confidential information, proprietary business information, preclinical and clinical trial data and personal information in connection with our business activities (collectively, "Confidential Information").

We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our IT Systems and Confidential Information, including from breakdown, breach, interruption or damage from cyber incidents, including from diverse threat actors, such as sophisticated nation-state and nation-state-supported actors, opportunistic hackers and hacktivists, as well as through diverse attack vectors, such as social engineering or phishing, employee error or malfeasance, misconfigurations, "bugs" or other vulnerabilities in commercial software that is integrated into our IT Systems, theft or misuse, malware (including ransomware), unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromises. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g. ransomware), viruses, spamming, social engineering or phishing attacks, denial-of-service attacks or other means, and deliberate attacks and attempts to gain unauthorized access to IT Systems and Confidential Information, have increased in frequency, intensity, and sophistication. These threats pose a risk to the security of our and our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' IT Systems, and the confidentiality, availability and integrity of our Confidential Information. There can be no assurance that we will be successful in preventing cyberattacks or successfully mitigating their effects. There can also be no assurance that our, our programs', our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information.

The risk of a security breach or disruption to our IT Systems and Confidential Information, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, varying parts of our workforce (and that of our third-party providers') are currently working remotely on a part or full time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions due to the challenges associated with managing remote computing assets and security vulnerabilities that are present in many non-corporate and home networks. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques - including artificial intelligence - that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our Confidential Information that is stored on their IT Systems. Any loss of Confidential Information, including clinical trial data from our completed or ongoing clinical trials for any of our product candidates, could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the Confidential Information. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We have experienced and expect to continue to experience actual and attempted cyberattacks of our IT Systems, such as through phishing scams and ransomware. Although we do not believe that we have experienced any material system failure, accident or cybersecurity incidents to date, we cannot guarantee that we will not experience such incidents in the future. Any adverse impact to the availability, integrity or confidentiality of our or third-party IT Systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition.

Any cyberattack that leads to unauthorized access, use, or disclosure of Confidential Information, data breach or destruction or loss of Confidential Information could result in a violation of applicable U.S. and international privacy, data protection and other laws and regulations, require us to notify affected individuals or supervisory authorities, subject us to litigation and governmental investigations,

proceedings and regulatory actions by federal, state and local regulatory entities in the United States and by international regulatory entities, cause our exposure to material civil and/or criminal liability, damage our reputation, and cause us to breach our contractual obligations, which could result in significant legal and financial exposure and reputational damages. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to implement further data protection measures or to remediate any information security vulnerability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage wholly or in part, of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks and the mishandling of data by our employees and third-party service providers, then our business, financial condition, results of operations and prospects could be adversely affected.

Disruptions at the FDA, the SEC, and other U.S. and foreign government agencies caused by funding shortages, staffing limitations, global health concerns or government shutdowns could cause delays in our product candidate development or capital raising plans, or otherwise prevent new products and services from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business, financial condition, and operating results.

The ability of the FDA and comparable foreign authorities to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA and comparable foreign authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and comparable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize our company and continue our operations.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We or the third parties upon whom we depend may be adversely affected by a natural or man-made disaster or other catastrophic event and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current business operations are conducted in our offices in Berlin and New York. Any unplanned event, such as flood, fire, explosion, earthquake, epidemic, power shortage, telecommunication failure or other natural or man-made accidents or incidents, including events of civil unrest, that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or any future product candidates or interruption of our business operations. Such a disaster or catastrophic event could severely disrupt our operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural or man-made disaster, power outage, pandemic or other event occurred that prevented us from using all or a significant portion of our physical space, that damaged critical infrastructure, such as the manufacturing facilities of our programs or any of their third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are not able to maintain and enhance our reputation and brand recognition, our business, financial condition and results of operations will be harmed.

We believe that maintaining and enhancing our reputation and brand recognition is critical to our relationships with existing and future investments, third-party therapy sites, therapists, patients and collaborators, and to our ability to attract clinics to become our third-party therapy sites offering our therapies. The promotion of our brand may require us to make substantial investments, and we anticipate that, as our market becomes increasingly competitive, these marketing initiatives may become increasingly difficult and expensive. Brand promotion and marketing activities may not be successful or yield increased revenue, and to the extent that these activities yield increased revenue, the increased revenue may not offset the expenses we incur and our business, financial condition and results of operations could be harmed. In addition, any factor that diminishes our reputation or that of our management, including our or our failing to meet the expectations of our network of third-party therapy sites, therapists and patients, could harm our reputation and brand and make it substantially more difficult for us to attract new third-party therapy sites, therapists and patients. If we do not successfully maintain and enhance our reputation and brand recognition, our business may not grow, and we could lose our relationships with third-party therapy sites, therapists and patients, which would harm our business, financial condition and results of operations.

Risks Related to Our International Operations

Our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company incorporated in the Netherlands, our business is subject to risks associated with being organized outside of the United States. Our business strategy incorporates potential international expansion to target patient populations outside the United States. If we receive regulatory approval for and commercialize any of our product candidates in patient populations outside the United States, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- our failure to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, including the ongoing military conflict between Russia and Ukraine, conflict in the Middle East, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations, including taxes;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our potential international expansion and operations and, consequently, our results of operations.

We are subject to the FCPA and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally

prohibit us and our employees and intermediaries from corruptly authorizing, promising, offering, or providing, directly or indirectly, anything of value, to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also requires us to maintain accurate books and records and implement a system of internal accounting controls. In the future, we and our strategic partners may operate in jurisdictions that pose a heightened risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties. We can be held liable under the FCPA or local anti-corruption laws for the corrupt or illegal activities for these third parties, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing international operations, including regulations administered by the governments of the Netherlands, Germany, the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, or, collectively, the Trade Control laws. Our global operations expose us to the risk of violating, or being accused of violating, Trade Control laws.

We have implemented policies and procedures reasonably designed to promote compliance with the FCPA, other anti-corruption laws, and Trade Control laws. Despite our compliance efforts, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil fines and penalties, injunctions, disgorgement and other sanctions and remedial measures, collateral litigation, damages, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control laws by the Netherlands, Germany, United States or other authorities could also have an adverse impact on our reputation, our business, financial condition and results of operations.

Risks Related to Our Common Shares

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline.

Sales of a substantial number of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common shares. This could also impair our ability to raise additional capital through the sale of our equity securities. In addition, the stock market in general has experienced, and will continue to experience from time to time, extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors have adversely impacted, and may continue to impact, the market price of our common shares, regardless of our operating performance. In February 2025, pursuant to our Shelf Registration Statement and a prospectus supplement filed with the SEC on February 13, 2025, we completed an underwritten public offering of 26,190,477 common shares. The common shares were sold at a public offering price of $2.10 per share. We received aggregate net proceeds of $51.4 million from the offering, after deducting underwriting discounts and commissions. In connection with the offering, we also granted to the Underwriter an option exercisable for 30 days to purchase up to an additional 3,928,571 common shares from us at the public offering price, less underwriting discounts and commissions. The Underwriter elected to purchase all additional shares we received net aggregate proceeds of $7.8 million, after deducting underwriting discounts and commissions. Following the date of this offering, the public trading price of our common shares decreased. If we sell, or the market perceives we intend to sell, substantial amounts of our common shares under our Shelf Registration Statement or otherwise, the market price of our common shares could decline significantly.

Our operating results and the price of our common shares may be volatile, and the market price of our common shares may drop below the price you pay.

Our quarterly operating results are likely to fluctuate in the future in response to numerous factors, many of which are beyond our control. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could subject the market price of our common shares to wide price fluctuations regardless of our operating performance.

These and other factors, many of which are beyond our control, may cause our operating results and the market price and demand for our common shares to fluctuate substantially. Fluctuations in our quarterly operating results could limit or prevent investors from readily selling their common shares and may otherwise negatively affect the market price and liquidity of common shares. In addition, in the past, when the market price of common shares has been volatile, holders have sometimes instituted securities class action litigation against the company that issued the common shares. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our business, profitability and reputation.

Additionally, due to several factors, including market conditions, if our share price falls below the minimum share price requirement as required by Nasdaq, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair shareholders' ability to trade in our securities. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from Nasdaq, for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. If our securities become illiquid, shareholders may be unable to trade their securities unless a market can be established or sustained, and similarly if investors are precluded from trading their securities, it could have dire consequences on our ability to raise more capital.

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, and reduced executive compensation disclosure. We could remain an emerging growth company for up to five years following the initial public offering of our common shares, although circumstances could cause us to lose that status earlier.

We are also a "smaller reporting company," as defined in the Exchange Act. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions and reduced disclosure requirements. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

We are not, and do not intend to become, regulated as an "investment company" under the Investment Company Act, and if we were deemed to be an "investment company" under the Investment Company Act, applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business.

An entity generally will be deemed to be an "investment company" for purposes of the Investment Company Act if:

- it is an "orthodox" investment company because it is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities; or
- it is an inadvertent investment company because, absent an applicable exemption, (i) it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis, or (ii) it owns or proposes to acquire investment securities having a value exceeding 45% of the value of its total assets (exclusive of U.S. government securities and cash items) and/or more than 45% of its incomes is derived from investment securities on a consolidated basis with its wholly owned subsidiaries.

We believe that we are engaged primarily in the business of developing treatments for mental health disorders and not in the business of investing, reinvesting or trading in securities. We hold ourselves out as a clinical-stage biopharmaceutical company and do not propose to engage primarily in the business of investing, reinvesting or trading in securities. Accordingly, we do not believe that we are an "orthodox" investment company as defined in Section 3(a)(1)(A) of the Investment Company Act and described in the first bullet point above.

Furthermore, we believe that (i) on an unconsolidated basis less than 40% of our total assets (exclusive of U.S. government securities and cash items) are composed of assets that could be considered investment securities, and/or (ii) on a consolidated basis,, (A) less than 45% of our total assets (exclusive of U.S. government securities and cash items) are composed of, and less than 45% of our income is derived from, assets that could be considered investment securities, and/or (B) we satisfy the conditions of the nonexclusive safe harbor from "investment company" status provided in Rule 3a-8 under the Investment Company Act, which applies to certain research and development companies. We further believe that we maintain majority control for purposes of Section 3(a)(1)(C) under the Investment Company Act, or primary control for purposes of Rule 3a-1 and Rule 3a-8 thereunder, over the majority of the atai companies, and that none of the atai companies over which we have majority or primary control is in the business of investing, reinvesting or trading in securities or otherwise an investment company such that our interests in such atai companies are not considered investment securities for purposes of the Investment Company Act. Accordingly, we do not believe that we are an inadvertent investment company by virtue of the 40% test in Section 3(a)(1)(C) under the Investment Company Act, the 45% tests in Rule 3a-1 thereof, as described in the second bullet point above, and/or the

nonexclusive safe harbor set forth in Rule 3a-8 thereof. In addition, we believe that we are not an investment company under Section 3(b)(1) of the Investment Company Act because we are primarily engaged in a non-investment company business.

Pursuant to Section 3(a)(1)(C) under the Investment Company Act, an entity will not be considered an investment company if, on an unconsolidated basis, less than 40% of its total assets (exclusive of U.S. government securities and cash items) are composed of assets that are investment securities. Section 3(a)(1)(C) provides that securities issued by a company that (i) is a majority-owned subsidiary of the issuer, (ii) is not itself an investment company, and (iii) does not rely on the exceptions from the definition of "investment company" set forth in either Section 3(c)(1) or Section 3(c)(7) of the Investment Company Act. In order for a company to be deemed to be a "majority-owned subsidiary" of the issuer, the issuer must at a minimum own at least 50% of the voting securities of the company.

Pursuant to Rule 3a-1 under the Investment Company Act, an entity will not be considered an investment company if, on a consolidated basis with its wholly owned subsidiaries, less than 45% of its total assets (exclusive of U.S. government securities and cash items) are composed of assets that are investment securities, or the Asset Test, and less than 45% of its income is derived from investment securities, or the Income Test. Rule 3a-1 also provides that securities issued by a company (i) that is "controlled primarily" by the issuer, (ii) through which the issuer engages in a business other than that of investing, reinvesting, owning, holding, or trading in securities, and (iii) that is not, itself, an investment company will not be deemed investment securities for purposes of the Asset and Income Tests. In order for a company to be presumed to be "controlled primarily" by the issuer, the issuer must at a minimum control at least 25% of the voting securities of the company, and the degree of the issuer's control must be greater than that of any other person.

We believe that we maintain majority control for purposes of Section 3(a)(1)(C) under the Investment Company Act, or primary control for purposes of Rule 3a-1 and Rule 3a-8 thereunder, over the majority of the atai companies, and that none of the atai companies over which we have majority or primary control is in the business of investing, reinvesting or trading in securities or is otherwise an investment company. We monitor and will continue to monitor our holdings in such atai companies in an effort to ensure continuing and ongoing control over such atai companies for purposes of compliance with the requirements of Section 3(a)(1)(C), Rule 3a-1 and/or Rule 3a-8. Additionally, we believe that we qualify for the nonexclusive safe harbor set forth in Rule 3a-8 under the Investment Company Act because we are engaged primarily in the business of developing treatments for mental health disorders and our historical development, public representations of policy, the activity of our officers and directors, the nature of our present assets, the sources of our present income, and the public perception of the nature of our business all support the conclusion that we are an operating company and not an investment company.

As a result, we do not believe our interests in such atai companies will be deemed investment securities for purposes of Section 3(a)(1)(C), Rule 3a-1 and/or Rule 3a-8. Accordingly, we believe that (i) on an unconsolidated basis less than 40% of our total assets (exclusive of U.S. government securities and cash items) are composed of assets that could be considered investment securities, and/or (ii) on a consolidated basis, (A) less than 45% of our total assets (exclusive of U.S. government securities and cash items) are composed of, and less than 45% of our income is derived from, assets that could be considered investment securities, and/or (B) we satisfy the conditions of the nonexclusive safe harbor from "investment company" status provided in Rule 3a-8 under the Investment Company Act; and we do not believe that we are deemed to be an investment company.

The Investment Company Act and the rules thereunder contain detailed parameters for the organization and operation of investment companies. Among other things, the Investment Company Act and the rules thereunder limit or prohibit transactions with affiliates, impose limitations on the issuance of debt and equity securities, generally prohibit the issuance of options and impose certain governance requirements. We intend to conduct our operations so that we will not be deemed to be an investment company under the Investment Company Act or otherwise conduct our business in a manner that does not subject us to the registration and other requirements of the Investment Company Act. In order to ensure that we are not deemed to be an investment company, we may be limited in the assets that we may continue to own and, further, may need to dispose of or acquire certain assets at such times or on such terms as may be less favorable to us than in the absence of such requirement. If anything were to happen which would cause us to be deemed to be an investment company under the Investment Company Act (such as significant changes in the value of the atai companies or a change in circumstance that results in a reclassification of our interests in the atai companies for purposes of the Investment Company Act), the requirements imposed by the Investment Company Act could make it impractical for us to continue our business as currently conducted, which would materially adversely affect our business, financial condition and results of operations. In addition, if we were to become inadvertently subject to the Investment Company Act, any violation of the Investment Company Act could subject us to material adverse consequences, including potentially significant regulatory penalties and the possibility that certain of our contracts could be deemed unenforceable.

We may be classified as a passive foreign investment company ("PFIC") which could result in adverse U.S. federal income tax consequences to U.S. holders of common shares.

We may be classified as a passive foreign investment company ("PFIC") which could result in adverse U.S. federal income tax consequences to U.S. holders of common shares.

A non-U.S. corporation will be classified as a passive foreign investment company, or a PFIC, for any taxable year if either:

a) at least 75% of its gross income is "passive income" for purposes of the PFIC rules or

b) at least 50% of the value of its assets (determined on the basis of a quarterly average) is attributable to assets that produce or are held for the production of passive income.

The PFIC rules also contain a look-through rule whereby the Company will be treated as owning its proportionate share of the gross assets and earning its proportionate share of the gross income of any other corporation in which it owns, directly or indirectly, 25% or more (by value) of the stock.

If we are a PFIC for any taxable year during which a U.S. holder holds our common shares, certain adverse U.S. federal income tax consequences could apply to such U.S. holder.

To alleviate such adverse tax consequences, U.S. holders in certain circumstances may make a "qualified electing fund" election or, if shares of the PFIC are "marketable stock" for purposes of the PFIC rules, may make a mark-to-market election with respect to the shares of the PFIC. Based on our historic and anticipated operations and composition of assets and a review of income sources and asset categories, we may be a PFIC for the current taxable year and in the foreseeable future. If we determine that we are a PFIC for any taxable year, we will use reasonable efforts to provide U.S. holders with information as the U.S. Internal Revenue Service may require, including a PFIC annual statement, in order to enable the U.S. holders to make the qualified electing fund election. However, there can be no assurance that we will be able to timely provide such required information to the U.S. holders.

In 2022, the U.S. Treasury released proposed regulations that may change certain aspects of the PFIC rules described above, including the application of certain elections to partnerships and other pass through entities. It is unclear whether such proposed regulations will be finalized. U.S. holders should consult their tax advisors regarding the potential consequences of PFIC status, including with respect to making a qualified electing fund or mark-to-market election.

If a United States person is treated as owning at least 10% of our common shares, such holder may be subject to adverse U.S. federal income tax consequences.

Depending upon the aggregate value and voting power of our common shares that United States persons are treated as owning (directly, indirectly or constructively), we could be treated as a controlled foreign corporation ("CFC"). Additionally, because our group consists of one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as CFCs and lead to adverse U.S. tax consequences for threshold United States holders of common shares, regardless of whether or not we are treated as a CFC. If a United States person (as defined in the United States Internal Revenue Code of 1986, as amended, or the Code) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such person may be treated as a "United States shareholder" with respect to applicable CFCs in our group. Such shareholders are potentially subject to current taxation on their pro rata share of certain CFC income and additional U.S. reporting obligations.

If you are treated as a United States shareholder of a CFC (as defined above), failure to comply with these reporting obligations may subject you to significant monetary penalties and may extend the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due. Additionally, a United States shareholder of a CFC that is an individual would generally be denied certain tax deductions or foreign tax credits in respect of its income that may otherwise be allowable to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist holders of our common shares in determining whether we or any of our non-U.S. subsidiaries are treated as CFCs or whether any holder of our common shares is treated as a United States shareholder with respect to any such CFC, nor do we expect to furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. The U.S. Internal Revenue Service has provided limited guidance regarding the circumstances in which investors may rely on publicly available information to comply with their reporting and taxpaying obligations with respect to foreign-controlled CFCs. U.S. investors in our common shares should consult their advisors regarding the potential application of these rules to their investment in the common shares.

Evolving global tax legislation could increase our overall tax burden.

Global tax legislative changes could negatively impact our business. The OECD, with the support of the Group of Twenty ("G20"), initiated the base erosion and profit shifting ("BEPS") project in 2013 in response to concerns that changes were needed to international tax laws. In November 2015, the G20 finance ministers adopted final BEPS reports designed to prevent, among other things, the artificial shifting of income to low-tax jurisdictions, and legislation to adopt and implement the standards set forth in such reports has been enacted or is currently under consideration in a number of jurisdictions. In June 2016, the Council of the European Union adopted Directive (EU) 2016/1164 which established rules against aggressive tax planning practices including, but not limited to, profit shifting and hybrid instruments and structures. In May 2019, the OECD released a two-pillar framework to address taxation challenges associated with the digital economy. Pillar One focused on the allocation of group profits among taxing jurisdictions based on a market-based concept rather than the historical "permanent establishment" concept. Pillar Two, among other things, introduced a global minimum tax. While we do not currently meet the revenue thresholds to fall within the scope of some of the aforementioned provisions, the foregoing tax changes and other possible future tax changes may have an adverse impact on us.

We do not anticipate paying any cash dividends in the foreseeable future. If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our common shares in both Germany and the Netherlands.

We currently intend to retain our future earnings, if any, for the foreseeable future, to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common shares. As a result, capital appreciation in the price of our common shares, if any, will be your only source of gain on an investment in our common shares. However, if we do pay dividends, we may need to withhold tax on such dividends both in Germany and the Netherlands.

Dividends paid by us to our shareholders are subject to Dutch dividend withholding tax on the basis that we are a company incorporated under Dutch law. Given that we are also considered a tax resident of Germany on the basis of that fact that our place of effective management is in Germany, the tie-breaker rule taken up in the double tax treaty between Germany and the Netherlands (the "Convention"), concludes that we are solely considered a tax resident of the jurisdiction where our place of effective management is situated and restricts the Netherlands to levy Dutch dividend withholding tax on dividends distributed by us to our shareholders as long as our place of effective management is in Germany. The restriction for the Netherlands to levy Dutch dividend withholding tax does not apply to dividends distributed by us to shareholders who are deemed to be a resident in the Netherlands for Dutch tax purposes or if the common shares are attributable to a permanent establishment situated in the Netherlands of a holder that is not deemed resident of the Netherlands.

Our shareholders will need to be identified in order to establish whether we need to withhold Dutch dividend withholding tax on dividends distributed. If we are not able to identify our shareholders, we are required to withhold both Dutch as well as German dividend withholding tax which may have an adverse consequence on the actual amount received by our shareholders.

Furthermore, the Multilateral Convention to Implement Tax Treaty Related Measures ("MLI") may have an impact on the restriction for the Netherlands to levy Dutch dividend withholding tax on dividends paid by us to our shareholders by amending the tie-breaker rule taken up in the Convention. If both Germany as well as the Netherlands list the Convention as covered by the MLI, or a Covered Convention, and opt-in to apply the amendment to the tie-breaker rule, the MLI would amend the tie-breaker rule taken up in the Convention on the basis of which we are considered a tax resident of Germany by introducing a mandatory MAP procedure. As it currently stands, the MLI is not applicable to the Convention because Germany did not include the Convention in the list of tax treaties covered by the MLI. If Germany changes its position in the future, we will not be entitled to any relief or exemption from tax provided by the Convention, including the withholding tax restriction, as long as Germany and the Netherlands do not reach an agreement on our tax residency for purposes of the Convention except to the extent and in such manner as may be agreed upon by the authorities. As a result, any dividends distributed by us during the period in which no such agreement has been reached between Germany and the Netherlands may be subject to withholding tax both in Germany and the Netherlands.

We may become taxable in a jurisdiction other than Germany and/or re-domicile our company to a jurisdiction other than the Netherlands and this may increase the aggregate tax burden on us and/or our shareholders.

We are subject to tax rules in the jurisdictions in which we qualify as a tax resident. We may in the future consider amendments to our articles, subject to applicable law, to (i) transition our governance model from a two-tier board model (with separate management and supervisory boards) to a one-tier board model (with a unitary board of directors comprising executive and non-executive directors) and (ii) eliminate certain limitations that were designed to reflect our status as a German tax resident. We also may make other changes to our governance model, including changes that may cause our place of "effective management" to no longer be in Germany. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline, and dividends distributed by us, and interest or royalty payments made by us, if any, may become subject to withholding taxes in more than one jurisdiction.

Moreover, these changes do not imply that our company will continue to exist as a company incorporated under Dutch law. We and our management continue to assess opportunities to optimize our organizational and corporate structure and we may pursue a re-domiciliation of our company from the Netherlands to another jurisdiction. If such a re-domiciliation would be effected, this would have additional tax consequences for us and our shareholders and would alter the rights and protections afforded to our shareholders under Dutch law, as our new jurisdiction of incorporation will have different legal and governance requirements. This could include changes in shareholder voting rights, fiduciary duties of our directors and/or the ability of shareholders to bring certain legal claims. The foregoing could create uncertainty and adversely impact our business operations, financial condition, and the market value of our securities. Investors should carefully consider these risks when evaluating an investment in our company.

Our ability to use our net operating loss carryforward and other tax attributes may be limited.

We have net operating losses, or NOLs, in various jurisdictions including Germany and the United States. As of December 31, 2024, our German NOL carryforward was approximately $184.0 million. German tax law imposes certain limits on the utilization of NOLs that are carried forward or carried back to a particular year. Our ability to utilize NOLs may be further limited under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz – KStG*) and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz –*

GewStG). These additional limitations may apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable.

Generally, a qualified ownership change occurs if more than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding. In the case of such a qualified ownership change, tax loss carryforwards expire in full. To the extent that the tax loss carryforwards do not exceed hidden reserves (*stille Reserven*) taxable in Germany, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carryforwards will be preserved if certain conditions are satisfied. In case of a qualified ownership change, tax loss carryforwards will be preserved (in the form of a *fortführungsgebundener Verlustvortrag*) if the business operations have not been changed and will not be changed within the meaning of Section 8d KStG.

According to an appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 1 KStG is not in line with the German constitution. In addition, our ability to utilize our NOLs and certain other tax attributes in the United States could be subject to limitation or expire unused under U.S. tax law. As of December 31, 2024, we had U.S. federal NOLs of $64.7 million. In addition, under Section 382 of the United States Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a cumulative change, by value, in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income or taxes may be limited. If an ownership change occurs and our ability to use our net operating loss carryforward is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

One of our principal shareholders has a significant holding in the company which may give them influence in certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances.

As of December 31, 2024, Apeiron held an 20.1% interest in our Company. In February 2025, in connection with our underwritten public offering, Apeiron purchased an additional 10,835,718 common shares. As of March 1, 2025, Apeiron held a 22.7% interest in our Company. Accordingly, Apeiron may, as a practical matter, be able to influence certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances. Such concentration of ownership may also have the effect of delaying or preventing any future proposed change in control. The trading price of our common shares could be adversely affected if potential new investors are disinclined to invest in us because they perceive disadvantages to a large shareholding being concentrated in the hands of a single shareholder. The interests of Apeiron and the investors that acquire our common shares may not be aligned. Apeiron may make acquisitions of, or investments in, other businesses in the same sectors as us or our programs. These businesses may be, or may become, competitors of us or our programs. In addition, other entities managed or advised by Apeiron may be in direct competition with us or our programs on potential acquisitions of, or investments in, certain businesses.

Claims of U.S. civil liabilities may not be enforceable against us.

We are organized and existing under the laws of the Netherlands. As such, under Dutch private international law, the rights and obligations of our shareholders vis-à-vis the Company originating from Dutch corporate law and our articles of association, as well as the civil liability of our officers (*functionarissen*) (including our managing directors, supervisory directors and executive officers) are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us, our managing directors and supervisory directors and executive officers may be limited under applicable law.

We are not a resident of the United States and our officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against us and/or our officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States. Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

As a result, it may not be possible for shareholders to effect service of process within the United States upon us or our managing directors, supervisory directors and executive officers or to enforce against them or us judgments rendered by U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, it is not clear whether a Dutch court would impose civil liability on us or any of our managing directors, supervisory directors and executive officers in an original action based solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in the Netherlands.

The United States and the Netherlands do not, as of the date of this filing, have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, it is noted that both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments

Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to a United States judgment if (i) the jurisdiction of the United States court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the United States court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such United States judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the United States court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a United States court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a United States judgment is given binding effect, a claim based thereon may, however, still be rejected if the United States judgment is not or no longer formally enforceable.

A competent Dutch court may deny the recognition and enforcement of punitive damages or other awards. Moreover, a competent Dutch court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Finally, there may be specific other instances, including pursuant to anti-boycott rules and regulations, where Dutch law prohibits the recognition and enforcement of a United States judgment. Therefore, United States investors may not be able, or experience difficulty, to enforce a judgment obtained in a United States court against us or our officers.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our executive officers, directors, senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our executive officers, directors, senior management and the experts named herein.

Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us or our executive officers, directors or certain experts named herein who are residents of or possessing assets in the Netherlands, Germany, or other countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.

We are a public company (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our articles of association the rules of our management board and our supervisory board and our other internal rules and policies and by Dutch laws. However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of managing directors and supervisory directors may be different from the rights and obligations of shareholders and directors in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our managing directors and supervisory directors are required by Dutch law to consider the interests of our Company and its business, considering the interests of our shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or remove our managing directors or supervisory directors.

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, certain provisions of our articles of association may make it more difficult for a third-party to acquire control of us or effect a change in our management board and supervisory board. These include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board, which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital;
- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient);
- a provision allowing, among other matters, the former chairperson of our supervisory board to manage our affairs if all of supervisory directors are removed from office or otherwise incapacitated or prevented from acting and to appoint others to be charged with the supervision of our affairs, until new supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above; and
- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board with the approval of our supervisory board.

In addition, Dutch law allows for staggered multi-year terms of our managing directors and supervisory directors, as a result of which only some of our managing directors and supervisory directors may be subject to appointment or re-appointment in any one year.

We do not comply with all best practice provisions of the Dutch Corporate Governance Code ("DCGC").

We are subject to the DCGC. The DCGC contains principles and best practice provisions on corporate governance that regulate relations between the management board, the supervisory board and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a “comply or explain” principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If a company subject to the DCGC does not comply with those provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such noncompliance. The DCGC applies to Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all best practice provisions of the DCGC. See “Description of Share Capital and Articles of Association.” This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

Dutch and European insolvency laws are substantially different from U.S. insolvency laws and may offer our shareholders less protection than they would have under U.S. insolvency laws.

We are subject to Dutch insolvency laws in the event any insolvency proceedings are initiated against us, including, among other laws and regulations, Regulation (EU) 2015/848 of the European Parliament and of the Council of May 20, 2015 on insolvency proceedings. Should a court in another Member State of the European Union determine that our center of main interests is situated in that Member State, the courts in that Member State will in principle have jurisdiction over the insolvency proceedings initiated against us and the insolvency laws of that Member State will in principle apply to us, in accordance with and subject to such the aforementioned Regulation and the rules promulgated thereunder. Insolvency laws in the Netherlands or the relevant other Member State of the European Union, as applicable, may offer our shareholders less protection than they would have under U.S. insolvency laws and make it more difficult for our shareholders to recover the amount they could expect to recover in a liquidation or restructuring under U.S. insolvency laws.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for each Annual Report on Form 10-K we file with the SEC. This assessment includes disclosure of any material weaknesses identified by our management in internal control over financial reporting. In the future, when we are no longer an emerging growth company, our independent registered public accounting firm will also be required to attest to the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K to be filed with the SEC pursuant to Section 404(b) of the Sarbanes-Oxley Act. We are also required to disclose material changes made in our internal control over financial reporting on a quarterly basis. Failure to comply with the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC, the stock exchange on which our securities are listed or other regulatory authorities, which would require

additional financial and management resources. Compliance with Section 404 requires that we incur substantial costs and expend significant management efforts.

We can give no assurance that material weaknesses will not be identified in the future. We continue to implement measures designed to improve our internal controls over financial reporting A material weakness in our internal control over financial reporting could result in an increased probability of fraud, litigation from our shareholders, reduction in our ability to obtain financing, and require additional expenditures to remediate. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in loss of investor confidence in the accuracy and completeness of our financial reports and a decline in our share price, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

General Risk Factors

If we engage in additional acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may continue to engage in various additional acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. For example, in October 2024, we acquired all of the issued and outstanding shares of IGX, a subsidiary of IntelGenx, in exchange for our senior secured debt in IGX being discharged. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent or unknown liabilities;
- the issuance of our equity securities which would result in dilution to our shareholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel and operating systems;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs; and
- our incurrence of large one-time expenses and acquisition of intangible assets that could result in significant future amortization expense.

If any one or more of the above risks were to materialize, we may experience an adverse impact on our business, financial condition or results of operations.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business and other factors beyond our control, such as general conditions in the global economy and in the global financial markets, a weakened demand for any of our current or future product candidates, the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the ACA, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience difficulties in any eventual commercialization of our product candidates and our business, financial condition, results of operations and cash flows could be adversely affected.

Furthermore, the global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, rising inflation and interest rates, and uncertainty about economic stability. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, cost increases due to high and persistent inflation and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot

anticipate all of the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

In addition, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico and a 10% tariff on imports from China, which was subsequently increased to 20%. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. For example, IntelGenx, a Canadian company which we acquired in October 2024, is a drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and for our development candidate, VLS-01. These tariffs may increase the cost of such products and negatively impact our results of operations.

Moreover, persistent economic downturns may require us to undertake optimization and cost saving initiatives, including streamlining our organization and adjusting the size and structure of our workforce. For example, throughout 2022 to 2024, we implemented certain cost reduction efforts to reduce material spend and operating expenses. In February 2024, we eliminated approximately 10% of our global workforce in order to reduce redundancies among certain positions. Any reduction in force may yield unintended consequences and costs, such as attrition beyond the intended reduction in force, the distraction of employees and reduced employee morale, which could, in turn, adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge or inefficiency during transitional periods. Any of these impacts could also adversely affect our reputation as an employer, make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the restructuring.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our common shares or publishes inaccurate or unfavorable research about our business, our share price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which might cause our share price and trading volume to decline.

We will continue to incur increased costs as a result of operating as a public company and our management team is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a U.S. public company we have, and expect to continue to, incur significant legal, accounting, reporting and other expenses, particularly after we no longer qualify as an emerging growth company. We also incur costs and expenses for managing directors' and supervisory directors' fees, increased director and officer insurance costs, investor relations costs, and various other costs of a public company.

The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel have and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations, often subject to varying interpretations and continuously evolving over time, have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business, including our preclinical studies, clinical trials, trial sites, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

We have faced and may face in the future risks related to pandemics, epidemics or outbreaks of infectious diseases. For example, the COVID-19 pandemic presented substantial public health and economic challenges and affected our employees, clinical trial participants, and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. The full extent to which any future pandemics, epidemic disease outbreaks or public health crises may negatively impact the broader global economy and our business and operations, including our research and development programs and related clinical trials, will largely depend on future developments and actions taken in response to such events, which are highly uncertain and cannot be predicted.

We continue to work closely with third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to the production of our product candidates and any future therapeutic candidates caused by pandemics or epidemics. Any supply disruptions may adversely impact the shipment of drug substances or any current or future product candidates or therapeutic candidates for use in our, our collaborator', or any future collaborators' preclinical studies or clinical trials, or our ability to generate sales of and revenue from our approved products, if any, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Any future pandemics may also affect employees and patients involved in our clinical trials. Any negative impact the a pandemic has on patient enrollment or treatment or the development of our product candidates and any future therapeutic candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates and any future therapeutic candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results. Any future pandemic may also cause significant volatility in public equity markets and disruptions to the United States and global economies, which could adversely impact our share price and our ability to raise capital on favorable terms, or at all, when needed.

The increasing focus on environmental, social, and governance ("ESG") initiatives could increase our costs, harm our reputation and adversely impact our financial results.

The increasing focus on ESG initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social, and governance and other sustainability matters, such as climate change and diversity, equity, and inclusion. We may experience pressure to make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. Moreover, stakeholders have varying perspectives on environmental, social, and other sustainability matters, and both advocates and opponents of such matters are increasingly resulting to an array of activism forms; any failure to successfully navigate these expectations may result in adverse impacts. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. Such requirements and other expectations are not uniform, and may be inconsistently interpreted or applied, which can increase the complexity and cost of compliance. If we fail to comply with new laws, regulations or reporting requirements, or new interpretations of existing standards, our reputation and business could be adversely impacted. Additionally, many of our business partners and suppliers may be subject to similar reporting and stakeholder expectations, which may augment or create additional risks, including risks that may not be known to us.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.

Climate change has the potential to negatively affect our business and results of operations. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change.

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs.

Certain policymakers have also adopted, or are considering adopting, legal or regulatory requirements regarding various aspects of climate change, which could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, increased carbon disclosure and transparency, and upgrade of facilities to meet new building codes, which could increase our operating costs. Parts of our supply chain and other of our stakeholders are also subject to similar risks, which may increase or result in additional risks.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

As part of our risk management program, we reference security industry frameworks and other guidance to help us assess, identify, and manage cybersecurity risks. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use these frameworks as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include, but are not limited to:

- risk assessments designed to help identify material cybersecurity risks to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors based on their criticality and risk profile.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. We face certain ongoing risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See "Risk Factors – *Cyberattacks, data security incidents or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption, legal liability, damage to our reputation, and significant disruption of our business operations which could materially affect our operating results, financial condition, and business*."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Committee) oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program.

The Committee receives regular reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our General Counsel, Chief Financial Officer, Head of IT, other internal security staff or external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including other internal staff such as the Head of IT and Chief Operating Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's and their delegates' collective experience include over ten years of cybersecurity, incident response, and the safeguarding of organizational assets expertise. Specifically, our Head of IT has over ten years of experience leading cybersecurity teams and programs, while our Chief Operating Officer has over seven years of experience risk management and three years of cybersecurity oversight.

Our management team stays informed and monitors efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties.

Our principal executive office is located at Wallstraße 16, 10179, Berlin, Germany where we lease approximately 7,400 square feet of office space. The lease commenced in February 2023, and we will make payments over a five year term. We also lease office space in New York, New York. We believe that these facilities will be adequate for our near-term needs and that we will be able to renew these leases. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

In October 2024 we acquired IntelGenx Corp. and assumed leases of approximately 43,000 square feet of office, lab, and manufacturing spaces in Montreal, Canada. The leases are set to expire in February 2026.

Item 3. Legal Proceedings.

We are, from time to time, party to various claims and legal proceedings arising in the ordinary course of our business. Given that such proceedings are subject to uncertainty, there can be no assurance that such legal proceedings, either individually or in the aggregate, will not have a material adverse effect on our business, results of operations, financial condition or cash flows. See Note 18, *Commitments and Contingencies – Legal Proceedings*, to our audited consolidated financial statements for additional information.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common shares began trading on The Nasdaq Global Market under the symbol "ATAI" on June 18, 2021. Prior to that time, there was no established public trading market for our common shares.

Holders of Record

As of March 11, 2025, there were 81 holders of record of our common shares. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common shares whose shares are held in the names of various security brokers, dealers and registered clearing agencies.

Dividend Policy

We have never paid or declared any cash dividends on our common shares in the past, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. However, if we do pay a dividend or other distribution from our reserves on our common shares in the future, whether in cash, assets or otherwise, then under Dutch law, we may only do so to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to such restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of our management board with the approval of our supervisory board and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our management board and supervisory board deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included elsewhere in this Form 10-K. This discussion contains forward-looking statements based upon current plans, expectations and beliefs involving risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and in other parts of this Form 10-K.

All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. Unless the context otherwise requires, all references in this subsection to "we," "us," "our," "atai" or the "Company" refer to atai and its consolidated subsidiaries.

Business Overview

We are a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes. Founded in 2018, atai emerged from the urgent need for better mental health solutions for patients who are under-served by current treatment options. We are advancing a pipeline of product candidates designed to address the complex nature of mental health disorders. We believe that these investigational compounds have the potential to become rapid-acting, durable, and commercially scalable therapies for mental health patients in need of new treatment options.

Mental health disorders are highly prevalent and estimated to affect more than one billion people globally. The economic burden of these disorders is substantial and growing rapidly. Between 2009 and 2019, spending on mental health care in the United States increased by more than 50%, reaching $225 billion, and a Lancet Commission report estimates that the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors ("SSRIs") and serotonin-norepinephrine reuptake inhibitors ("SNRIs") are well established and effective for certain patients, approximately 65% of patients do not achieve remission of their symptoms after up to four antidepressant treatment trials, translating to a significant unmet medical need.

Our research is focused on developing rapid-acting, robust, and durable mental health treatments that can deliver large-scale patient impact. We are committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change. We pursue this in two ways: we develop novel product candidates in-house and we make strategic investments in companies developing promising product candidates.

We have built a diversified pipeline of psychedelic product candidates that target mental health disorders that we believe have significant unmet medical need. Our in-house programs include: VLS-01 (N,N-Dimethyltryptamine ("DMT")) for treatment-resistant depression ("TRD"); EMP-01 (R-3,4-methylenedioxy-methamphetamine ("R-MDMA")) for social anxiety disorder ("SAD"); and a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD.

We believe psychedelics are emerging as novel breakthrough therapies for mental health disorders, such as depression, supported by growing scientific evidence, recent regulatory advancements and increasing patient and physician acceptance. Clinical studies have demonstrated the potential safety and efficacy profile of psychedelics, particularly their rapid onset of effect and sustained efficacy after a short course of administration. We believe these programs, which include both novel molecular entities and optimized variants of known compounds, have the potential to address significant unmet needs in mental health treatment.

Our commitment to innovation extends to early-stage drug discovery through our discovery platform. Intellectual property development has been essential to our strategy since inception, particularly through key investments in novel chemical entity ("NCE") development. We have made substantial progress in our drug discovery efforts to date, synthesizing and screening more than 750 compounds and identifying novel scaffolds that display potential in targeting mental health disorders.

We have a strategic investment in Beckley Psytech Limited ("Beckley Psytech"), a private clinical-stage biopharmaceutical company developing two investigational compounds: BPL-003, 5 Methoxy N,N-dimethyltryptamine ("mebufotenin") benzoate, for TRD and alcohol use disorder ("AUD"), and ELE-101, psilocin, for the treatment of major depressive disorder ("MDD"). Our investment in Beckley Psytech is included in Other Investments in our consolidated balance sheets.

We have a strategic investment in Recognify Life Sciences, Inc. ("Recognify"), a company developing RL-007, an investigational pro-cognitive neuromodulator for the treatment of cognitive impairment associated with schizophrenia ("CIAS"). We hold a 51.9% ownership percentage in Recognify, and have consolidated this subsidiary into our consolidated financial statements with the noncontrolling interest reflected in our consolidated balance sheets and the portion of net earnings attributable to the noncontrolling interests reflected in our consolidated statements of operations.

We own IntelGenx Corp. ("IGX"), a subsidiary of IntelGenx Technologies Corp. ("IntelGenx"), a novel drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and for our development candidate, VLS-01.

We have incurred significant operating losses since our inception. Our net loss attributable to ATAI Life Sciences N.V. stockholders was $149.3 million and $40.2 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, our accumulated deficit was $700.2 million and $550.9 million, respectively. Our ability to generate product revenue sufficient to achieve profitability will depend substantially on the successful development and eventual commercialization of product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

Our historical losses resulted principally from costs incurred in connection with research and development activities, as well as general and administrative costs associated with our operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access, commercialization, and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our operating losses stem primarily from the development of our mental health research programs. Furthermore, we expect to continue to incur costs associated with operating as a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through a combination of equity offerings, debt financing, strategic collaborations and alliances or licensing arrangements. Our inability to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. There can be no assurances, however, that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from the sale of our common shares, issuances of convertible notes and a term loan.

Capital Allocation and Strategic Value Capture

Consistent with our strategy, we provide the necessary funding and operational support to our programs to maximize their probability of success in clinical development and commercialization. We also regularly review the status of our programs to assess whether there are alternative forms of ownership, partnership or other forms of collaboration that would optimize our economic interests and the success of our programs. To that end, we are focusing on clinical phase programs and business development that we expect to generate meaningful data in the near term, and, therefore, prioritizing programs and opportunities that we believe have the highest return potential and value. As a result, in late 2023, we finalized and entered into agreements through which we disposed of our equity interests in Psyber, Inc. and TryptageniX Inc. In 2024, our strategic investment in Beckley Psytech Limited added more programs to our diverse portfolio of clinical-stage psychedelic product candidates with multiple upcoming clinical readouts. We are also exploring other opportunities, including but not limited to seeking strategic partnership options, for example, with Recognify Life Sciences, Inc. and Perception Neuroscience Holdings, Inc. In 2024, we finalized and entered into agreements through which we disposed of our equity interest in Psyprotix, Inc. and Kures, Inc.

In February 2023, we implemented a realignment initiative resulting in a reduction in force of approximately 30% of our global workforce in order to more effectively allocate our research and development and other resources supporting the revised business and program priorities and to reduce operational costs. In February 2024, we conducted a reduction in force of approximately 10% of our global workforce, predominantly reducing redundancy in our general & administrative functions to reduce operational costs. Refer to Note 22 in the Notes to the consolidated financial statements in Part II, Item 8 for further information.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) and follow the requirements of the United States Securities and Exchange Commission ("SEC"), and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of our financial position, results of operations and comprehensive loss, and cash flows for the periods presented.

Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification (“ASC”), and Accounting Standards Update (“ASU”) issued by the Financial Accounting Standards Board (“FASB”).

The results of operations for the years ended December 31, 2024 and 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2025 or for any other future annual or interim period.

Consolidation

Our consolidated financial statements include the accounts of atai and our subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

Our policy is to consolidate all entities that we control by ownership of a majority of the outstanding voting stock. In addition, entities that meet the definition of a variable interest entity (“VIE”) for which we are the primary beneficiary are consolidated. The primary beneficiary

is the party who has the power to direct the activities of a VIE that most significantly impact the entity's economic performance and who has an obligation to absorb losses of the entity as well as a right to receive benefits from the entity that could potentially be significant to the entity. For consolidated entities that are less than wholly-owned, the third-party's holding of equity interest is presented as Noncontrolling interests in our consolidated balance sheets and consolidated statements of stockholders' equity. The portion of net earnings attributable to the noncontrolling interests is presented as Net loss attributable to noncontrolling interests in our consolidated statements of operations.

Ownership interests in entities over which we have significant influence, but not a controlling financial interest, are accounted for under either the alternative measurement under ASC 321 or as an equity method investment. Investments eligible for the measurement alternative under ASC 321 are carried at its initial cost, with remeasurements to fair value upon impairment or upon a price change observed in an orderly transaction of the same or similar investments. For equity method investments where we have not elected the fair value option, we record gains (losses) from investments in equity method investees, net of tax, for our proportionate share of the underlying company's net results until the investment balance is adjusted to zero. If we make subsequent additional investments in that same company, we may record additional gains (losses) based on changes to our investment basis and also may record additional income (loss) in equity method investments. If we have elected the fair value option for an equity investment, the fair value of the investments will be recognized upon acquisition and any changes in fair value will be recognized as a component of other income (expense), net.

Components of Our Results of Operations

Revenue

On March 11, 2021, we entered into a license and collaboration agreement (the "Otsuka Agreement"), with Otsuka Pharmaceutical Co., LTD ("Otsuka"), under which we granted exclusive rights to Otsuka to develop and commercialize certain products containing arketamine in Japan for the treatment of depression and other select indications. We received an upfront, non-refundable payment of $20.0 million in June 2021 and we are also eligible to receive up to $35.0 million if certain development and regulatory milestones are achieved and up to $66.0 million in commercial milestones upon the achievement of certain commercial sales thresholds. We are eligible to receive tiered royalties ranging from low-teens to high-teens on net sales of licensed products subject to reduction in certain circumstances. In January 2025, Otsuka provided a notice of termination pursuant to the Otsuka Agreement, effective April 24, 2025. Following the effective termination date, we will no longer be eligible to receive any milestone payments or royalties pursuant to the Otsuka Agreement.

We do not expect to generate any further revenue under the Otsuka Agreement. We do not expect to generate any revenue from the sale of products unless and until such time that our product candidates have advanced through clinical development and regulatory approval, if ever. We expect that any revenue we generate, if at all, will fluctuate from year-to-year as a result of the timing and amount of payments relating to such services and milestones and the extent to which any of our products are approved and successfully commercialized. Our ability to generate future revenues will also depend on our ability to complete preclinical and clinical development of product candidates or obtain regulatory approval for them.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including our agreements with third parties, such as consultants and contract research organizations ("CROs");
- expenses incurred under agreements with consultants who supplement our internal capabilities;
- the cost of laboratory supplies and acquiring, developing, and manufacturing preclinical study materials and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- payments made in connection with third-party licensing agreements.

Research and development costs, including costs reimbursed under the Otsuka Agreement, are expensed as incurred, with reimbursements of such amounts being recognized as revenue. We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, contract manufacturing organizations ("CMOs") and research laboratories

in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under third-party license agreements.

Certain internal research and development expenses consisting of employee and contractor-related costs are not allocated to specific product candidate programs because these costs are deployed across multiple product candidate programs under research and development expense.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future in connection with our planned preclinical and clinical development activities in the near term and in the future.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates. This is due to the numerous risks and uncertainties associated with developing products, including the uncertainty of whether (i) any clinical trials will be conducted or progress as planned or completed on schedule, if at all, (ii) we obtain regulatory approval for our product candidates and (iii) we successfully commercialize product candidates.

General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, related benefits and stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions, professional fees for legal, patent, accounting, auditing, tax and consulting services, travel expenses, facility-related expenses, and information technology-related expenses.

Other income (expense), net

Interest income

Interest income consists of interest earned on cash balances held in interest-bearing accounts and interest earned on notes receivable. We expect that our interest income will fluctuate based on the timing and ability to raise additional funds as well as the amount of expenditures for the research and development of our product candidates and ongoing business operations.

Interest expense

Interest expense consists primarily of interest expense incurred in connection with our 2022 Term Loan Facility with Hercules Capital, Inc.

Benefit from research and development tax credit

Benefit from research and development tax credit consists of tax credits received in Australia under the Research and Development Tax Incentive ("RDTI") program and research and development tax credits received in Canada following our acquisition of IGX. Qualifying expenditures include employment costs for research staff, consumables, and relevant, permitted CRO costs incurred as part of research projects.

Change in fair value of assets and liabilities, net:

The Company carries various assets and liabilities at fair value and subsequent remeasurements are recorded as a Change in fair value of assets and liabilities, net as a component of Other income (expense), net. Assets held at fair value include securities held at fair value, investments held at fair value, and convertible notes receivable. Liabilities held at fair value include contingent considerations and convertible promissory notes and derivative liability.

Change in fair value of securities carried at fair value

Change in fair value of securities consists of changes in fair value of our available for sale securities for which we have elected the fair value option.

Change in fair value of other investments held at fair value

Change in fair value of other investments held at fair value consists of subsequent remeasurements of our investments held at fair value, including COMPASS Pathways plc ("COMPASS") and IntelGenx prior to the completion of our acquisition of IGX, for which we have elected the fair value option, as well as additional contingent warrants held with Beckley Psytech.

Change in fair value of convertible notes receivable - related party

Change in fair value of convertible notes receivable - related party consists of subsequent remeasurements of our convertible notes receivable with IntelGenx, for which we elected the fair value option, prior to the completion of our acquisition of IGX.

Change in fair value of contingent consideration liability - related party

Change in fair value of contingent consideration liability - related party consists of subsequent remeasurements of our contingent consideration liability related to our acquisition of Perception Neuroscience Holdings, Inc. ("Perception") for which we record at fair value.

Change in fair value of contingent consideration liabilities

Change in fair value of contingent consideration liabilities consists of subsequent remeasurements of our contingent consideration liabilities related to our acquisition of DemeRx IB, Inc. ("DemeRx IB") and TryptageniX, Inc. ("TryptageniX") for which we record at fair value.

Change in fair value of convertible promissory notes and derivative liability

Change in fair value of convertible promissory notes and derivative liability consists of subsequent remeasurements of certain convertible notes issued in 2020, some of which are held by a related party.

Gain on settlement of pre-existing contract

Gain on settlement of pre-existing contract consists of a non-cash gain recognized upon the acquisition of IGX related to the settlement of an existing contract with IntelGenx.

Impairment of other investments

Impairment of other investments consists of a reduction in the carrying value of our investments that do not have a readily determinable fair value and are accounted for under the measurement alternative under ASC 321, including DemeRx NB, Inc. ("DemeRx NB").

Gain on deconsolidation of a variable interest entity, net

Gain (loss) on deconsolidation of a variable interest entity is the result of removing assets and liabilities from our consolidated balance sheets following a loss of control or divestment of a variable interest entity.

Gain on dissolution of a variable interest entity

Gain on dissolution of a variable interest entity is the result of removing assets and liabilities from our consolidated balance sheets following a dissolution of a variable interest entity.

Foreign exchange gain (loss), net

Foreign exchange gain (loss), net consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated assets and liabilities, relative to the U.S. dollar. The impact of foreign currency exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated assets and liabilities.

Other income (expense), net

Other income (expense), net consists principally of the changes in the carrying values of our assets and liabilities and net gains (losses) recognized on the sale of certain of our assets.

Benefit from (provision for) income taxes

For our consolidated entities, deferred income taxes are provided for the effects of temporary differences between the amounts of assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax purposes. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

We regularly assess the need to record a valuation allowance against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Accordingly, we maintain a full valuation allowance against net deferred tax assets for all entities as of December 31, 2024. In assessing the realizability on deferred tax assets, we consider whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. The future realization of deferred tax assets is subject to the existence of sufficient taxable income of the appropriate character (e.g., ordinary income or capital gain) as provided under the carryforward provisions of local tax law. We consider the scheduled reversal of deferred tax liabilities (including the effect in available carryback and carryforward periods), future projected taxable income, including the character and jurisdiction of such income, and tax-planning strategies in making this assessment.

Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the considerations described above. The balances of unrecognized tax benefits for the years ended

December 31, 2024 and 2023 are an immaterial amount and $0.4 million, respectively, which represent the amounts that, if recognized, impact the effective income tax rate in future periods. For the years ended December 31, 2024 and 2023 we accrued an immaterial amount and $0.1 million for interest and penalties, respectively.

Losses from investments in equity method investees, net of tax

Losses from investments in equity method investees, net of tax consists of our share of equity method investees losses on the basis of our equity ownership percentage and IPR&D charges resulting from basis differences related to our equity method investments.

Net loss attributable to noncontrolling interests

Net loss attributable to noncontrolling interests consists of the portion of net loss that is allocated to the noncontrolling interests of certain consolidated variable interest entities ("VIEs"). Net losses in consolidated VIEs are attributed to noncontrolling interests considering the liquidation preferences of the different classes of equity held by the shareholders in the VIE and their respective interests in the net assets of the consolidated VIE in the event of liquidation, and their pro rata ownership. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by changes in the net loss of our VIEs and our ownership percentage changes.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	For the Year ended December 31,			
	2024	2023	$ Change	% Change
	(in thousands, except percentages)			
License revenue	$ 308	$ 314	$ (6)	(2%)
Operating expenses:				
Research and development	55,455	62,203	(6,748)	(11%)
General and administrative	47,544	63,582	(16,038)	(25%)
Total operating expenses	102,999	125,785	(22,786)	(18%)
Loss from operations	(102,691)	(125,471)	22,780	(18%)
Other income (expense), net:				
Interest income	778	1,847	(1,069)	(58%)
Interest expense	(3,124)	(2,656)	(468)	18%
Benefit from research and development tax credit	525	2,445	(1,920)	(79%)
Change in fair value of assets and liabilities, net	(48,879)	86,583	(135,462)	(156%)
Gain on settlement of pre-existing contract	5,567	—	5,567	100%
Impairment of other investments	—	(1,011)	1,011	(100%)
Gain on deconsolidation of a variable interest entity, net	—	60	(60)	(100%)
Gain on dissolution of a variable interest entity	1,166	—	1,166	100%
Foreign exchange loss, net	(1,263)	(894)	(369)	41%
Other income (expense), net	(484)	(189)	(295)	156%
Total other income (expense), net	(45,714)	86,185	(131,899)	(153%)
Net loss before income taxes	(148,405)	(39,286)	(109,119)	278%
Benefit from (provision for) income taxes	356	(1,016)	1,372	(135%)
Losses from investments in equity method investees, net of tax	(2,000)	(3,593)	1,593	(44%)
Net loss	$ (150,049)	$ (43,895)	$ (106,154)	242%
Net loss attributable to noncontrolling interests	(780)	(3,671)	2,891	(79%)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (149,269)	$ (40,224)	$ (109,045)	271%

License revenue

License revenue was $0.3 million and $0.3 million for the years ended December 31, 2024, and 2023, respectively, which is related to the reimbursement of research and development expenses under the Otsuka Agreement. For the years ended December 31, 2024, and 2023, respectively, there were no milestones achieved under the Otsuka Agreement.

Research and development expenses

The table and discussion below present research and development expenses of our consolidated entities for the years ended December 31, 2024 and 2023:

	For the year ended December 31,			
	2024	2023	$ Change	% Change
	(in thousands, except percentages)			
Direct research and development expenses by program:				
Core Psychedelic Programs				
VLS-01	$ 10,606	$ 9,055	$ 1,551	17%
EMP-01	1,527	2,635	(1,108)	(42%)
Discovery (Non-Hallucinogenic)	2,649	144	2,505	1741%
Non-Psychedelic Program				
RL-007	10,962	8,394	2,568	31%
Other Programs	5,396	9,840	(4,445)	(45%)
Enabling Technologies and Drug Discovery Platforms	598	3,099	(2,501)	(81%)
Unallocated research and development expenses:				
Personnel expenses	20,935	26,415	(5,480)	(21%)
Professional and consulting services	1,052	1,952	(900)	(46%)
Depreciation	184	—	184	100%
Other	1,546	669	877	131%
Total research and development expenses	$ 55,455	$ 62,203	$ (6,749)	(11%)

Research and development expenses were $55.5 million for the year ended December 31, 2024, compared to $62.2 million for the year ended December 31, 2023. The decrease of $6.7 million was primarily attributable to a $5.5 million decrease in personnel expenses (inclusive of a $2.0 million decrease in stock-based compensation and a $1.6 million decrease in restructuring charges), a $2.5 million decrease related to our enabling technologies and drug discovery platform as discussed below, and a $0.9 million decrease in professional and consulting fees. These decreases were partially offset by a $1.1 million net increase of direct costs in our Core Psychedelic and Non-Psychedelic programs as discussed below, a $0.9 million increase in other expenses related to impairment of certain intangible assets, and a $0.2 million increase in depreciation expense.

Core Psychedelic Programs

VLS-01: DMT for TRD

The $1.6 million net increase in direct costs was primarily due to a $3.6 million increase of clinical development costs related to our Phase 1b trial of VLS-01 designed to evaluate the efficacy, safety, tolerability, PK and PD of VLS-01 delivered using our proprietary OTF formulation, as well as costs related to our Elumina trial, the randomized, double-blind, placebo-controlled Phase 2 study of VLS-01. These increases were partially offset by a $1.5 million decrease in manufacturing costs and $0.5 million decrease in preclinical development costs.

EMP-01: MDMA for PTSD

The $1.1 million decrease in direct costs for our EMP-01 program was primarily due to a $1.2 million net decrease in clinical development costs relating to the wind-down and completion of our Phase 1 single ascending dose trial, and the start-up of an exploratory, randomized, double-blind, placebo-controlled Phase 2 study in the United Kingdom to assess the safety, tolerability and efficacy of EMP-01 and a $0.2 million decrease in preclinical development costs. These decreases were offset by a $0.3 million increase in manufacturing costs.

Discovery (Non-Hallucinogenic)

The $2.5 million increase in discovery costs was primarily due to a $2.5 million increase of preclinical development costs related to our novel 5-HT2A receptor agonists.

Non-psychedelic Program

RL-007: Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia

The $2.6 million increase in direct costs for our RL-007 program was primarily due to an increase of $2.3 million of clinical development costs, $0.2 million of manufacturing costs, and $0.2 million of preclinical development costs, all relating to our Phase 2b proof-of-concept clinical trial for RL-007 in CIAS.

Other Programs

The $4.4 million decrease in direct costs for our other programs was primarily due to a $5.2 million decrease in our PCN-101 program, $1.7 million decrease in our EGX-121 program, $0.2 million decrease in our KUR-101 program, and $0.1 million decrease in our RLS-01

program. These decreases were partially offset by a $2.6 million increase in IBX-210 costs and $0.2 million of IGX costs recognized following the completion of our acquisition in October 2024.

Enabling Technologies and Drug Discovery Platforms

The $2.5 million decrease in our enabling technologies and drug discovery platforms primarily relates to the wind-down costs of our Invyxis, TryptageniX, InnarisBio, and Psyber programs.

General and administrative expenses

General and administrative expenses were $47.5 million for the year ended December 31, 2024 compared to $63.6 million for the year ended December 31, 2023. The decrease of $16.1 million was primarily related to a $9.0 million decrease in personnel expenses (inclusive of a $5.4 million decrease in stock-based compensation and a $0.4 million increase in restructuring expenses), a $7.2 million decrease in professional services, and a $1.4 million decrease in insurance expenses; partially offset by a $1.1 million increase in non-income tax expense and a $0.5 million increase in investor relations and public company fees.

We expect that our general and administrative expenses will not materially increase in the near future. We may add more general and administrative head count in the future to support the potential commercialization of our product candidates.

Other income (expense), net

Interest income

Interest income for the years ended December 31, 2024 and 2023 primarily consisted of interest earned on our cash balances and notes receivable during these periods. We recognized interest income of $0.8 million and $1.8 million for the years ended December 31, 2024 and 2023, respectively.

Interest expense

Interest expense for years ended December 31, 2024 and 2023 primarily consisted of interest expense incurred in connection with our 2022 Term Loan Facility with Hercules Capital, Inc. Interest expense was $3.1 million and $2.7 million for the years ended December 31, 2024 and 2023, respectively.

Benefit from research and development tax credit

We recognized a research and development tax credit from the Canadian Tax Authorities and Australian Tax Authorities as a benefit of $0.5 million for the year ended December 31, 2024. We recognized a research and development tax credit from the Australian Tax Authorities as a benefit of $2.4 million for the year ended December 31, 2023.

Change in fair value of assets and liabilities, net:

Change in fair value of securities carried at fair value

Changes in fair value of securities consists of changes in the fair value of our available for sale securities for which we have elected the fair value option. During the years ended December 31, 2024 and 2023, we recognized a gain of $3.8 million and $5.4 million, respectively, relating to the change in fair value of our available for sale securities.

Change in fair value of short-term notes receivable - related party, net

Changes in fair value of short-term notes receivable - related party, net, including interest, consists of subsequent remeasurement of our short-term notes receivable with IntelGenx, prior to the completion of our acquisition, for which we have elected the fair value option. During the year ended December 31, 2024 we recognized a $0.5 million loss related to the change in the fair value. We recorded an immaterial change in the fair value of short-term notes receivable - related party during the year ended December 31, 2023.

Change in fair value of short-term convertible notes receivable - related party

Changes in fair value of short-term convertible notes receivable - related party, including interest, consists of subsequent remeasurement of our convertible notes receivable with IntelGenx, prior to the completion of our acquisition, for which we have elected the fair value option. During the year ended December 31, 2024 we recognized a $13.2 million loss related to the change in the fair value. We recognized an immaterial change in fair value for our short term convertible notes receivable - related party during the year ended December 31, 2023.

Change in fair value of other investments held at fair value

Changes in fair value of other investments held at fair value consists of subsequent remeasurement of our investments held at fair value, including our American Depository Shares ("ADS") holdings in COMPASS, IntelGenx related investments, prior to the completion of our acquisition, and additional contingent warrants issued by Beckley Psytech. During the year ended December 31, 2024, we recognized a $39.4 million loss related to our ADS holdings in COMPASS, a $6.5 million loss related to our investments in IntelGenx, prior to the

completion of our acquisition, and a $1.7 million gain related to additional contingent warrants issued by Beckley Psytech Limited. During the year ended December 31, 2023, we recognized a $81.9 million non-cash change in fair value of other investments held at fair value related to an accounting method change for our ADS holdings in COMPASS resulting in our election of fair value accounting following our loss of significant influence over COMPASS.

Change in fair value of contingent consideration liability—related party

The milestone and royalty payments in relation to the acquisition of Perception were recognized at the acquisition date, and are subsequently remeasured to fair value. For the years ended December 31, 2024 and 2023, we recognized a $0.5 million gain and an immaterial gain, respectively.

Change in fair value of contingent consideration liabilities

In October 2023, we acquired shares of the noncontrolling interest of DemeRx IB making DemeRx IB a wholly owned subsidiary. An earn-out of up to $8.0 million was part of the consideration and was recognized at fair value at the transaction date and subsequently remeasured at fair value. For the years ended December 31, 2024 and 2023, we recognized a $1.2 million gain and a $0.1 million loss, respectively, related to the DemeRx IB contingent consideration. In December 2023, we disposed of our equity interest in TryptageniX, but retained the contingent consideration liability, which is subsequently remeasured to fair value. For the years ended December 31, 2024 and 2023, we recognized a $0.2 million gain and an immaterial gain, respectively, related to the TryptageniX contingent consideration.

Change in fair value of convertible promissory notes and derivative liability

In December 2023 and April 2024, certain 2020 convertible noteholders exchanged the 2020 convertible notes issued by ATAI Life Sciences AG for notes issued by ATAI Life Sciences NV, which are convertible into ATAI NV common shares. We determined that this was a modification to the convertible notes. We bifurcated the note and the conversion option and record the change in fair value of the conversion option quarterly. For the years ended December 31, 2024 and 2023, we recognized a $3.4 million gain and a $0.7 million loss, respectively, due to a change in the fair value of the conversion option of the notes issued by ATAI Life Sciences NV.

Gain on settlement of pre-existing contract

For the year ended December 31, 2024, we recognized a $5.6 million non-cash gain upon the acquisition of IGX related to the settlement of an existing contract with IntelGenx. No such gain or loss was recognized for the year ended December 31, 2023.

Impairment of other investments

We did not recognize an Impairment of other investments for the year ended December 31, 2024. For the year ended December 31, 2023, we recognized a $1.0 million impairment of our DemeRx NB investment, which was transferred to DemeRx, Inc. in connection with our acquisition of the remaining equity in DemeRx IB.

Gain on deconsolidation of a variable interest entity, net

We did not recognize a Gain on deconsolidation of a variable interest entity, net for the year ended December 31, 2024. Gain on deconsolidation of a variable interest entity, net was $0.1 million for the year ended December 31, 2023 as a result of the gain upon deconsolidation of TryptageniX of $0.4 million, partially offset by the loss upon deconsolidation of Psyber, Inc. of $0.3 million.

Gain on dissolution of a variable interest entity

Gain on dissolution of a variable interest entity was $1.2 million for the year ended December 31, 2024 as a result of the gain upon dissolution of Kures. We did not recognize a Gain on dissolution of a variable interest entity for the year ended December 31, 2023.

Foreign exchange loss, net

We recognized a loss of $1.3 million related to foreign currency exchange rates for year ended December 31, 2024 and a loss of $0.9 million related to foreign currency exchange rates for the year ended December 31, 2023. This was primarily due to the impact of fluctuations in the foreign currency exchange rate between the Euro and the U.S. dollar on our foreign denominated balances.

Other income (expense), net

We recognized $0.5 million of other income (expense), net for year ended December 31, 2024, which primarily relates to a $2.1 million non-cash loss on the sale of our ADS holdings in COMPASS. This loss was partially offset by a $1.3 million gain related to our investment in Beckley Psytech upon the issuance of deferred shares pursuant to the Escrow Agreement, and a gain of $0.3 million from the forgiveness of certain accounts payable amounts associated with the Kures dissolution. See Notes 5 and 6 in the Notes to our consolidated financial statements in Part II, Item 8 for further information.

We recognized $0.2 million of other expense, net for the year ended December 31, 2023, which consists primarily of a $0.3 million increase to the allowances on receivables, partially offset by a $0.1 million gain recognized on our divestment of our investment in Juvenescence Limited ("Juvenescence").

Benefit from (provision for) income taxes

We recognized a current income tax benefit of $0.4 million and a current income tax expense of $1.0 million for the years ended December 31, 2024 and 2023, respectively. The incremental benefit is a result of losses generated in Germany, U.K., and the U.S. and favorable return to provision adjustments from our U.S. tax returns. We recognized no deferred tax expense for years ended December 31, 2024 and 2023, respectively. Given our early-stage development and lack of prior earnings history, we have a full valuation allowance primarily related to German and international tax loss carryforwards and temporary timing differences related to stock-based compensation that we consider-more-likely-than-not not to be realized.

Losses from investments in equity method investees

Losses from investment in equity method investees for the years ended December 31, 2024 and 2023 were $2.0 million and $3.6 million, respectively. Loss from investment in equity method investees represents our share of equity method investee losses on the basis of our equity ownership percentages or based on our proportionate share of the respective class of securities in our other investments in the event that the carrying amount of our equity method investments was zero.

Net loss attributable to noncontrolling interests

Net losses attributable to noncontrolling interests for the years ended December 31, 2024 and 2023 were $0.8 million and $3.7 million, respectively which relate to the noncontrolling interests in Recognify, Perception, and Kures.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2024 and 2023, we had net losses attributable to ATAI Life Sciences N.V. shareholders of $149.3 million and $40.2 million, respectively. As of December 31, 2024 and 2023, our accumulated deficit was $700.2 million and $550.9 million, respectively. We expect to continue to incur losses and operating cash outflows for the foreseeable future as we continue working towards commercializing any of our product candidates. Our primary sources of liquidity are our cash and cash equivalents, short-term securities, convertible promissory notes, investments, sales of common shares, including under our at-the-market equity offering program, and the 2022 Term Loan Facility, as further described below. We maintain cash balances with financial institutions in excess of insured limits.

Our primary requirements for liquidity and capital are clinical trial costs, manufacturing costs, nonclinical and other research and development costs, funding of strategic investments, public company compliance costs and general corporate needs. Because our product candidates are in various stages of clinical and pre-clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaboration arrangements, license agreements, other business development opportunities with third parties and government grants.

Sources of Liquidity

Convertible Promissory Notes

In November 2018 and October 2020, we issued an aggregate principal amount of €1.0 million or $1.2 million (collectively, the "Convertible Notes"). The Convertible Notes are non-interest-bearing and have a maturity date of September 30, 2025, unless previously redeemed, converted, purchased or cancelled. Each note has a face value of €1 and is convertible into one ordinary share of ATAI Life Sciences AG upon the payment of €17.00. The noteholders have agreed that, subsequent to converting the notes into ATAI Life Sciences AG share, they will exchange the ATAI Life Sciences AG share for ATAI Life Science N.V. shares.

In December 2023 and April 2024, respectively, a noteholder and a related party noteholder each entered into an agreement with us to exchange their respective Convertible Notes for new convertible notes issued by ATAI Life Sciences N.V. Each new note has a face value of €1 and is convertible into 16 common shares of ATAI Life Sciences N.V. upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity.

As of December 31, 2024 the Convertible Notes had a principal balance of $0.4 million. If all convertible notes were converted, the Company would receive proceeds of €6.6 million ($6.9 million).

Investments

A significant potential source of non-dilutive funding resides in our investment in COMPASS's ADS, subject to market conditions. Based on quoted market prices, the market value of our ownership in COMPASS was $26.1 million as of December 31, 2024.

In September 2024, the Company sold 2,660,000 ADSs of COMPASS at a price of $6.05 per ADS in an open market transaction, resulting in net proceeds received of $16.1 million.

ATM Agreement

In November 2022, we entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may issue and sell our common shares, having an aggregate offering price of up to $150.0 million, from time to time through an "at-the-market" equity offering program under which Jefferies will act as sales agent. Subject to the terms and conditions of the Sales Agreement, Jefferies could sell the common shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. There have been no sales under the Sales Agreement through December 31, 2024.

Underwritten Offering

In February 2025, we entered into an underwriting agreement (the "Underwriting Agreement") with Berenberg Capital Markets LLC in connection with the issuance and sale by us in a public offering of 26,190,477 of our common shares, at a public offering price of $2.10 per share, less underwriting discounts and commissions. The common shares were offered pursuant to our Shelf Registration Statement as well as a prospectus supplement filed with the SEC on February 13, 2025. Under the terms of the Underwriting Agreement, we granted to the Underwriter an option exercisable for 30 days to purchase up to an additional 3,928,571 common shares from us at the public offering price, less underwriting discounts and commissions. Pursuant to the Underwriting Agreement, the Underwriter exercised the option to purchase an additional 3,928,571 common shares.

The net proceeds from the offering of our common shares were approximately $59.2 million, after deducting the underwriting discounts and commissions and offering expenses payable by us.

Hercules Term Loan

On August 9, 2022, we entered into the Loan Agreement with Hercules, which was amended in May 2023, August 2024, and January 2025. See " "—Liquidity and Capital Resources—Indebtedness—Hercules Term Loan" for additional information.

Liquidity Risks

As of December 31, 2024, we had cash and cash equivalents of $17.5 million, restricted cash of $10.0 million and short-term securities of $44.8 million. As of December 31, 2024, we believe our cash, cash equivalents and short-term securities and committed term loan funding will be sufficient to fund our operations for at least the next twelve months. Based on our current operating plan, we estimate that our existing cash, including proceeds from our public offering of our common shares, marketable securities, and committed term loan funding as of the date this Annual Report on Form 10-K is filed with the SEC will be sufficient to fund operations into 2027.

We expect to continue to incur substantial additional expenditures in the near term to support our ongoing activities. Additionally, we have incurred and expect to continue to incur additional costs as a result of operating as a public company. We expect to continue to incur net losses for the foreseeable future. Our ability to fund our product development and clinical operations as well as commercialization of our product candidates, will depend on the amount and timing of cash received from planned financings.

Our future capital requirements will depend on many factors, including:

- the time and cost necessary to complete ongoing and planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities for our ongoing and planned clinical trials, and potential future clinical trials;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third party reimbursement;
- the cash requirements for purchasing additional equity from certain atai companies upon the achievement of specified development milestone events;

- the cash requirements for developing our programs and our ability and willingness to finance their continued development;
- the cash requirements for any future acquisitions or discovery of product candidates; and
- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans. If we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies and other strategic transactions. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Cash Flows

The following table summarizes our cash flows for years ended December 31, 2024 and 2023:

	For the year ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (82,437)	$ (84,118)
Net cash provided by (used in) investing activities	59,172	(53,295)
Net cash provided by (used in) financing activities	5,374	(8,355)
Effect of foreign exchange rate changes on cash	362	189
Net decrease in cash, cash equivalents and restricted cash	$ (17,529)	$ (145,579)

Net Cash Used in Operating Activities

Net cash used in operating activities was $82.4 million for the year ended December 31, 2024, which consisted of a net loss attributable to stockholders of $150.0 million, adjusted by noncash benefit of $76.8 million and net cash outflows from the change in operating assets and liabilities of $9.2 million. The noncash loss primarily consisted of $51.6 million loss related to the net change in the fair value of our assets and liabilities carried at fair value, $25.5 million of stock-based compensation, $2.1 million of loss on sale of investment held at fair value, $2.0 million of losses from our equity method investments, $1.1 unrealized foreign exchange losses, $1.0 million of depreciation and amortization, $0.9 million impairment of intangible assets, and $0.4 million of noncash lease expense. These losses were partially offset by a $5.6 million gain on settlement of pre-existing contract, a $1.2 million gain on dissolution of a variable interest entity, and $1.0 million of other income (expense), net. The cash outflow from the change in operating assets and liabilities of $9.2 million was primarily due to a $6.2 million decrease in accrued liabilities and other liabilities and $1.9 million decrease in accounts payable; partially offset by a $1.1 million increase in prepaid expenses and other current assets.

Net cash used in operating activities was $84.1 million for the year ended December 31, 2023, which consisted of a net loss attributable to stockholders of $43.9 million, adjusted by noncash benefit of $47.7 million and net cash inflows from the change in operating assets and liabilities of $7.5 million. The noncash benefit primarily consisted of $86.6 million gain related to the net change in the fair value of our assets and liabilities carried at fair value, $0.5 million of other noncash expenses, and $0.1 million gain on deconsolidation of a variable interest entity, partially offset by $33.0 million of stock-based compensation, $3.6 million of losses from our equity method investments, $1.0 million impairment of other investments, $0.8 million unrealized foreign exchange losses, and $1.1 million of depreciation and amortization. The net cash inflows from the change in operating assets and liabilities of $7.5 million was primarily due to a $8.7 million decrease in prepaid expenses and other current assets and a $2.1 million increase in accounts payable; partially offset by a $3.3 million decrease in accrued liabilities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $59.2 million for the year ended December 31, 2024, primarily driven by $65.6 million of proceeds from sale and maturities of securities at fair value, $16.1 million of proceeds from the sale of ADSs of COMPASS, and $0.4 million of cash received in the acquisition of IGX; partially offset by $15.0 million cash paid to Beckley Psytech pursuant to the Secondary Sale and the Escrow Agreement, $5.7 million of cash paid for short-term notes receivable – related party, $2.0 million of cash paid for short-term convertible notes receivable and warrant – related party, and $0.1 million of cash paid for intangible assets.

Net cash used in investing activities was $53.3 million for the year ended December 31, 2023, primarily driven by $160.3 million of cash paid for securities carried at fair value, $25 million of cash committed in anticipation of the closing of Beckley Psytech investment in January 2024, $3.5 million of loans remitted to related parties, $2.0 million of cash paid for convertible notes receivable - related party, $1.0 million of cash paid for investments held at fair value, $0.4 million cash paid out in variable interest entity deconsolidation, $0.3 million of cash paid for capitalized internal-use software development costs, and $0.3 million of cash paid for property and equipment; partially offset by $139.0 million of proceeds from sale and maturities of securities at fair value, and $0.5 million of proceeds from sale of other investments.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities of $5.4 million for the year ended December 31, 2024 consisted of $5.0 million of proceeds from debt financing and $0.5 million of proceeds from stock option exercises; partially offset by $0.2 million of financing costs paid.

Net cash used in financing activities was $8.4 million for the year ended December 31, 2023, primarily due to $8.5 million of cash paid for acquisition of noncontrolling interest and $0.1 million of debt financing costs paid; partially offset by $0.2 million of proceeds from stock option exercises.

Indebtedness

Convertible Notes

In November 2018, we issued an aggregate principal amount of $0.2 million of 2018 Convertible Notes. In October 2020, we issued an additional principal amount of $1.0 million of 2018 and 2020 Convertible Notes. The 2018 and 2020 Convertible Notes are non-interest-bearing and have a maturity date of September 30, 2025, unless previously redeemed, converted, purchased or cancelled. Each note has a face value of €1 and is convertible into one common share of ATAI Life Sciences AG upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity, except during certain periods subsequent to the consummation of the IPO.

In December 2023 and April 2024, respectively, a noteholder and a related party noteholder each entered into an agreement with us to exchange their respective 2018 and 2020 Convertible Notes for new convertible notes issued by ATAI Life Sciences N.V. Each new note has a face value of €1 and is convertible into 16 common shares of ATAI Life Sciences N.V. upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity.

As of December 31, 2024, the new ATAI Life Sciences N.V. notes had a principal balance of $0.4 million. If all convertible notes were converted, the Company would receive proceeds of €6.6 million ($6.9 million).

Hercules Term Loan

On August 9, 2022 (the "Closing Date"), we, ATAI Life Sciences AG ("ATAI AG" and together with us, the "Borrowers") and certain of our subsidiary guarantors (collectively, the "Subsidiary Guarantors") entered into a Loan and Security Agreement (the "Hercules Loan Agreement"). The Hercules Loan Agreement provides for term loans in an aggregate principal amount of up to $175.0 million under multiple tranches (as amended by that certain First Amendment to Loan and Security Agreement, dated as of March 13, 2023, the "First Amendment," that Second Amendment to Loan and Security Agreement, dated as of May 26, 2023, the "Second Amendment," and that Third Amendment to Loan and Security Agreement, dated August 14, 2024, the "Third Amendment," and the Fourth Amendment to Loan and Security Agreement, dated January 6, 2025, the "Fourth Amendment" and collectively, the "2022 Term Loan Facility").

On May 26, 2023, we, ATAI AG, and the Subsidiary Guarantors entered into the Second Amendment, with the several banks and other financial institutions or entities from time to time parties to the Hercules Loan Agreement, defined below, (collectively, the "Lenders") and Hercules, in its capacity as administrative agent and collateral agent for itself and for the Lenders (the "Agent") which amended that certain Loan and Security Agreement, dated August 9, 2022 (as amended by the First Amendment, the "Existing Loan Agreement" and as amended by the Second Amendment, the "Hercules Loan Agreement") to, among other things, (i) extend the availability of Tranche 1B of $10.0 million, from May 1, 2023, under the Existing Loan Agreement, to November 15, 2024, (ii) extend the availability of Tranche 1C of $15.0 million, from December 15, 2023, under the Existing Loan Agreement, to December 15, 2024, (iii) provide Tranche 1D of $20.0 million, available upon the earlier of (x) the full draw of Tranche 1C and (y) the expiration of Tranche 1C availability, through February 15, 2025, (iv) extend the availability of Tranche 2 of $15.0 million, from June 30, 2024, under the Existing Loan Agreement, subject to certain conditions under the Hercules Loan Agreement, to the earlier of (x) the full draw of Tranche 1D and (y) the expiration of Tranche 1D availability, through March 15, 2025, subject to the Tranche 2 Draw Test, (v) extend the timeline to achieve the second amortization

extension condition, from June 30, 2024, in the Existing Loan Agreement, to December 15, 2024, (vi) amend the Tranche 2 Draw Test, satisfaction of which is a condition to draw Tranche 2 under the Hercules Loan Agreement and (vii) extend the financial covenant commencement date, from the later of (x) July 1, 2023, and (y) the date that the outstanding debt under the facility is equal to or greater than $40.0 million, in the Existing Loan Agreement, to the later of (x) May 1, 2024, and (y) the date that the outstanding debt under the facility is equal to or greater than $30.0 million, provided, that the financial covenant is waived if the Company has a market capitalization of at least $550.0 million.

On August 14, 2024 (the "Third Amendment Date"), the Borrowers and certain Subsidiary Guarantors entered into the Third Amendment with the Lenders and Hercules, in its capacity as the Agent, which amended that certain Loan and Security Agreement, dated August 9, 2022 to, among other things, (i) provide Tranche 1B of $5.0 million on the Third Amendment Date, (ii) reduce the remainder of available Tranche 1 to $25.0 million, and extend the availability thereof (x) with respect to Tranche 1C, to be available after the Third Amendment Date until March 31, 2025, and (y) with respect to Tranche 1D, to be available upon the earlier to occur of (1) March 31, 2025 and (2) full borrowing of Tranche 1C, until June 30, 2025, (iii) increase Tranche 2 to $30.0 million, and extend the availability thereof to be available upon the earlier to occur of (1) June 30, 2025, and (2) full borrowing of Tranche 1D, until September 30, 2025, subject to the Tranche 2 Draw Test, (iv) extend the availability of Tranche 3 of $100.0 million, through March 31, 2026, available subject to lender's investment committee approval, (v) extend the amortization date to September 1, 2025, and extend the timeline to achieve the second amortization extension condition, to June 30, 2025, upon the occurrence of which the amortization date may be extended to March 1, 2026, (vi) amend the financial covenant to commence on October 1, 2024, and require that so long as our market capitalization is less than $550.0 million, Borrowers shall maintain qualified cash equal to at least 50% of the sum of (x) the amount of outstanding debt under the facility plus (y) Qualified Cash A/P Amount (as defined in the Agreement), or upon the occurrence of certain conditions, 70% of the sum of (x) the amount of outstanding debt under the facility plus (y) Qualified Cash A/P Amount, and (vii) reduce the interest rate to equal the greater of (x) 9.05% or (y) prime rate plus 4.30% (or, upon achieving certain conditions, (y) shall equal prime rate plus 4.05%).

In January 2025 (the "Fourth Amendment Date"), the Borrowers and certain Subsidiary Guarantors entered into the Fourth Amendment with the Lenders and Hercules, in its capacity as the Agent, which amended that certain Loan and Security Agreement, dated August 9, 2022 (as amended by the First Amendment, the Second Amendment, the Third Amendment, and the Fourth Amendment the "2022 Term Loan Agreement") to, among other things, consent to the conversion of ATAI AG from a German stock corporation (Aktiengesellschaft – AG) into a German limited liability company (Gesellschaft mit beschränkter Haftung – GmbH).

We are permitted to engage in certain specified transactions (subject to mandatory prepayment in certain instances as well as certain limitations, including the pledge of equity interests of certain subsidiaries and VIEs), including but not limited to, (i) entering into non-exclusive and certain specified exclusive licensing arrangements with respect to intellectual property without the consent of the Lenders; and (ii) entering into certain permitted acquisitions.

The 2022 Term Loan Facility will mature on August 1, 2026 (the "Maturity Date"), which may be extended until February 1, 2027 if we raise at least $175.0 million of unrestricted new net cash proceeds from certain permitted sources after the Closing Date and prior to June 30, 2025, and satisfy certain other specified conditions (the "Extension Condition Two"). The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) the prime rate as reported in the Wall Street Journal plus 4.30% and (ii) 9.05%; provided, that if the Extension Condition Two is satisfied, the rate of interest in the foregoing clause (i) is prime rate as reported in The Wall Street Journal plus 4.05%. Accrued interest is payable monthly following the funding of each term loan advance. We may make payments of interest only, without any loan amortization payments until September 1, 2025, which date may be extended to March 1, 2026 if Extension Condition Two is achieved. At the end of the interest only period, we are required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly installments.

As collateral for the obligations under the 2022 Term Loan Facility, we have granted to the Agent for the benefit of the Lenders a senior security interest in substantially all of our cash and investment accounts and each Subsidiary Guarantor's property (including a pledge of equity interests of certain subsidiaries and VIEs), exclusive of intellectual property, with certain limited exceptions set forth in the Hercules Loan Agreement.

The 2022 Term Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent (the "Qualified Cash") at all times commencing from the Closing Date, which includes a cap on the amount of cash that can be held by, among others, certain of our foreign subsidiaries in Australia and the United Kingdom. In addition, the financial covenant under the 2022 Term Loan Agreement requires that beginning on October 1, 2024, we shall maintain Qualified Cash in an amount no less than the sum of (1) 50% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that have not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, upon the occurrence of certain conditions, we shall at all times maintain Qualified Cash in an amount no less than the sum of (1) 70% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that have not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, further, that the financial covenant shall not apply on any day that our market capitalization is at least $550.0 million measured on a consecutive 10-business day period immediately prior to

such date of measurement and tested on a daily basis. Upon the occurrence of an event of default, including a material adverse effect, subject to certain exceptions, on our and ATAI AG's, taken together, business, operations, properties, assets or financial condition, and subject to any specified cure periods, all amounts owed by us may be declared immediately due and payable by the Lenders. As of December 31, 2024, we were in compliance with all applicable covenants under the 2022 Term Loan Agreement.

In addition, we are required to make a final payment fee (the "End of Term Charge") upon the earlier of (i) the Maturity Date, (ii) the date that we prepay, in full or in part, the principal balance of the 2022 Term Loan Facility, or (iii) the date that the outstanding balance of the 2022 Term Loan Facility becomes due and payable. The End of Term Charge is 6.95% of the aggregate original principal amount of the term loans so repaid or prepaid under the 2022 Term Loan Agreement.

We may, at our option, prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.00% of the principal amount prepaid if the prepayment occurs on or prior to the first anniversary of the Closing Date, (ii) 1.0% of the principal amount prepaid if the prepayment occurs after the first anniversary and on or prior to the second anniversary of the Closing Date, and (iii) 0.5% of the principal amount prepaid if the prepayment occurs after the second anniversary and prior to the Maturity Date.

Material Cash Requirements from Known Contractual and Other Obligations

We are a party to many contractual obligations involving commitments to make payments to third parties. These obligations impact our short-term and long-term liquidity and capital resource needs. Certain contractual obligations are reflected on the consolidated balance sheets as of December 31, 2024, while others are considered future commitments. Our contractual obligations primarily consist of milestone payments under existing license agreements. For information regarding our other contractual obligations, refer to Note 12. *Leases*, Note 18. C*ommitments and Contingencies*, and Note 19. *License Agreements.*

We have entered into other contracts in the normal course of business with certain CROs, CMOs and other third parties for preclinical research studies and testing, clinical trials and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon written notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. The amounts and timing of such payments are not known.

In addition, under various licensing and related agreements to which we are a party, we are obligated to pay annual license maintenance fees and may be required to make milestone payments and to pay royalties and other amounts to third parties. The payment obligations under these agreements are contingent upon future events, such as our achievement of specified milestones or generating product sales, and the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below. For additional information regarding our license agreements described below, see Note 19 to our consolidated financial statements included elsewhere in this Annual Report. For additional information regarding our contingent commitments and future put rights or options associated with our investments, see Note 4 to our consolidated financial statements included elsewhere in this Annual Report.

Otsuka License and Collaboration Agreement

In March 2021, Perception entered into a license and collaboration agreement (the "Otsuka Agreement") with Otsuka under which Perception granted exclusive rights to Otsuka to develop and commercialize products containing arketamine, known as PCN-101 in Japan for the treatment of any depression, including treatment-resistant depression, or major depressive disorder or any of their related symptoms or conditions at its own cost and expense. Perception retained all rights to PCN-101 outside of Japan.

With the execution of the Otsuka Agreement, Perception received an upfront, non-refundable payment of $20.0 million. Perception is also entitled to receive aggregate payments of up to $35.0 million if certain development and regulatory milestones are achieved for the current or a new intravenous formulation of a product and up to $66.0 million in commercial milestones upon the achievement of certain commercial sales thresholds. Otsuka is obligated to pay Perception a tiered, double-digit royalty on net sales of products containing PCN-101 in Japan, subject to reduction in certain circumstances. In January 2025, Otsuka provided a notice of termination pursuant to the Otsuka Agreement, effective April 24, 2025. Following the effective termination date, we will no longer be eligible to receive any milestone payments or royalties pursuant to the Otsuka Agreement.

For the years ended December 31, 2024 and 2023, there were no additional milestones achieved under the Otsuka Agreement. We recognized revenues of $0.3 million and $0.3 million related to certain research and development services during the years ended December 31, 2024 and 2023, respectively.

National University Corporation Chiba University License Agreement

In August 2017, Perception entered into a license agreement or CHIBA License with the National University Corporation Chiba University ("CHIBA") relating to Perception's drug discovery and development initiatives. Under the CHIBA License, Perception has been granted a worldwide exclusive license under certain patents and know-how of CHIBA to research, develop, manufacture, use and commercialize therapeutic products. Perception paid an upfront license fee and is required to pay an annual maintenance fee until the filing of a new drug application with the Food and Drug Administration. In addition, Perception is also required to pay tiered royalties ranging in the low to mid-single-digit on future net sales of licensed products that are covered by a valid claim of a licensed patent, if any. Perception is also

obligated to make contingent milestone payments totaling up to $1.2 million upon the achievement of certain clinical or regulatory milestones for each of the first two licensed products and $1.0 million upon the achievement of certain clinical or regulatory milestones for each additional licensed product. The CHIBA License will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2024 and 2023, we did not make any material payments pursuant to the CHIBA License.

Allergan License Agreement

In February 2020, Recognify entered into a license agreement with Allergan Sales, LLC, or Allergan, which grants Recognify an exclusive sublicensable and worldwide license under certain patent rights and know-how controlled by Allergan to develop, manufacture and commercialize certain products for use in all fields including the treatment of certain diseases and conditions of the central nervous system. Recognify paid Allergan an upfront payment of $0.5 million and will pay Allergan a mid-single-digit royalty on the net sales of the licensed products. In addition, Recognify is obligated to pay Allergan a low teen percentage of the non-royalty sublicense payments it receives from a third party receiving a sublicense to practice the rights licensed to Recognify under the Allergan License Agreement. Upon the occurrence of certain change of control transactions involving Recognify, or sale, assignment or transfer (other than sublicense) to a third party of any rights licensed to Recognify under the Allergan License Agreement, Recognify is required to share with Allergan a low teen percentage of the proceeds it receives from such transactions. The Allergan License Agreement will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2024 and 2023, we had made no material payments pursuant to the Allergan License agreement.

Columbia Stock Purchase Agreement

In June 2020, Kures entered into a license agreement (the “License Agreement”) with Trustees of Columbia University (“Columbia”), pursuant to which, Kures obtained an exclusive license under certain patents and technical information to discover, develop, manufacture, use and commercialize such patents or other products in all uses and applications (“Columbia IP”). In addition, in consideration for the rights to the Columbia IP, Kures entered into a Stock Purchase Agreement (the “SPA”) with Columbia in contemplation of the License Agreement. Pursuant to the SPA, Kures issued to Columbia certain shares of the Kures’ capital stock, representing 5.0% of Kures common stock on a fully diluted basis. Furthermore, the SPA provided that from time to time, Kures shall issue to Columbia additional shares of Kures’ common stock, at a per share price equal to the then fair market value of each such share, which price shall be deemed to have been paid in partial consideration for the execution, delivery and performance by Columbia of the License Agreement, such that the common stock held by Columbia shall equal to 5.0% of the common stock on a fully diluted basis, at all times up to and through the achievement of certain funding threshold.

In April 2022, Kures issued shares of Series A-2 Preferred Stock to certain investors upon the achievement of Series A-2 milestone events. Accordingly, we issued certain anti-dilution common stock to Columbia worth $0.3 million. We expensed the cost incurred for acquiring the license as acquisition of in-process research and development expense at inception. Since, the additional anti-dilution shares were issued as partial consideration towards the same license arrangement, the cost of such additional shares of $0.4 million was also expensed as acquisition of in-process research and development expense during the year ended December 31, 2023.

In October 2024, in connection with the dissolution of Kures, Inc., Kures and Columbia mutually agreed to terminate the existing License Agreement ("the Termination Agreement"). Under the Termination Agreement, Kures assigned to Columbia all of Kures' intellectual property rights that were filed during the term of the License Agreement and agreed that all licenses granted to Kures by Columbia are terminated. In exchange, Kures received consideration through the relief and discharge of an immaterial amount of outstanding payment obligations due to Columbia.

During the years ended December 31, 2024 and 2023, we did not make any material payments in connection with the Columbia agreement.

Dalriada License Agreement

In December 2021, Invyxis, Inc. ("Invyxis") entered into an exclusive services and license agreement (the “Dalriada License Agreement”) with Dalriada Drug Discovery Inc. (“Dalriada”). Under the Dalriada License Agreement, Dalriada is to exclusively collaborate with Invyxis to develop products, services and processes with the specific purpose of generating products consisting of new chemical entities. Under the original agreement, Invyxis was obligated to pay Dalriada up to $12.8 million in service fees for research and support services. In May 2023, we executed an amendment to the Dalriada License Agreement, which reduced the amount Invyxis will pay Dalriada in service fees to $7.4 million. In addition, Invyxis will pay Dalriada development milestone payments and low single digit royalty payments based on net product sales. We have the right, but not the obligation, to settle future royalty payments based on net product sales with the our common shares. Invyxis, our wholly-owned subsidiary, and Dalriada will determine the equity settlement based on a price per share determined by both parties.

In December 2022, we executed an amendment to the Dalriada License Agreement, which reduced the upfront deposit from $1.1 million to $0.5 million. As such, the remaining $0.6 million was applied against research and development expense incurred. We will expense the remaining deposit as the services are performed as a component of research and development expense in the consolidated statements of operations.

During the years ended December 31, 2024 and 2023, we recorded $0.4 million and $2.0 million, respectively as research and development expense.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, costs and expenses and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2, "Basis of Presentation, Consolidation and Summary of Significant Accounting Policies" in our consolidated financial statements appearing under Part II, Item 8, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred.

We accrue expense for preclinical studies and clinical trial activities performed by vendors based upon estimates of the proportion of work completed. We determine such estimates by reviewing contracts, vendor agreements, and through discussions with our internal personnel and external service providers as to the progress or stage of completion and the agreed-upon fee to be paid for such services. However, actual costs and timing of preclinical studies and clinical trials are highly uncertain, subject to risks, and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the accrual is adjusted accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Acquisitions and Dispositions

We evaluate each of our acquisitions under the accounting framework in ASC 805, Business Combinations, to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, we first perform a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, we further evaluate whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, we conclude that the acquired set is a business. During the year ended December 31, 2024, we completed the acquisition of IGX, that was accounted for as a business combination. Refer to Note 3 in the Notes to the consolidated financial statements within Part II, Item 8 for more information. We account for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, we make significant estimates and assumptions. Our estimates of fair value are based upon assumptions believed to be reasonable, but these assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill. During the year ended December 31, 2023, we did not have any acquisitions that were accounted for as business combinations.

For asset acquisitions that involve the initial consolidation of a VIE that is not a business for which we are the primary beneficiary, the transactions are accounted for under ASC 810, Consolidation, and no goodwill is recognized. Rather, we recognize the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE was a business and subject to the guidance on recognition and measurement in a business combination under ASC 805, and recognize a gain or loss for the difference between (a) the sum of the fair values of consideration paid (including any contingent consideration) and noncontrolling interests, (b) the fair value of the VIE's identifiable assets and liabilities, and (c) the reported amounts of any previously held interests. Acquisition-related expenses incurred in asset acquisitions that involve the initial consolidation of a VIE that is not a business, are not included as a component of consideration transferred, but are accounted for as an expense in the period in which the costs are incurred. In an asset acquisition, including the initial consolidation of a VIE that is not a business, acquired IPR&D with no alternative future use is charged to research and development expense at the acquisition date.

Upon the occurrence of certain events and on a regular basis, we evaluate whether we no longer have a controlling interest in our consolidated VIEs. If we determine that we no longer have a controlling interest, the subsidiary is deconsolidated. We will record a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any

consideration received, (b) the fair value of any retained noncontrolling investment in our former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

Stock-Based Compensation

We recognize compensation costs related to stock-based awards granted to employees, directors, and consultants based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. We recognize expense for performance-based awards if the stated goals are determined to be probable of being met as of the period end. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed. For performance-based awards with market conditions, we determine the fair value of awards as of the grant date using a Monte Carlo simulation model. We have elected to recognize forfeitures of stock-based compensation awards as they occur.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires assumptions, including the fair value of our Common Shares prior to our initial public offering, volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These subjective assumptions are estimated as follows:

Expected term—We have generally elected to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected volatility—As we have limited trading history for our common shares, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We also included our own historical volatility in the determination of expected volatility.

Risk-free interest rate—The risk-free rate assumption is based on the implied yield with an equivalent expected term at the grant date.

Expected dividend yield—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options; therefore, we have estimated the dividend yield to be zero.

As part of the valuation of stock-based compensation under the Black-Scholes option-pricing model, it is necessary for us to estimate the fair value of our common shares. Prior to our IPO, we were required to periodically estimate the fair value of our common shares when issuing options and in computing our estimated stock-based compensation expense. Given the absence of a public trading market prior to the completion our initial public offering, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, we exercised reasonable judgment and considered numerous objective and subjective factors to determine our best estimate of the fair value of our common shares. The estimation of the fair value of our common shares considered factors including the following: the estimated present value of our future cash flows; our business, financial condition and results of operations; our forecasted operating performance; the illiquid nature of our common shares; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions. We apply similar methodology to estimate the fair value of our privately held subsidiaries' common shares. After the closing of the IPO, our board of directors determined the fair value of each common share underlying stock-based awards based on the closing price of our common shares as reported on Nasdaq on the date of grant.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Basis of Presentation, Consolidation and Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncements" in our consolidated financial statements appearing under Part II, Item 8.

JOBS Act

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period

provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates and foreign currency exchange rates. In addition, our portfolio of notes receivables is exposed to credit risk in the form of non-payment or non-performance. In mitigating our credit risk, we consider multiple factors, including the duration and terms of the note and the nature of and our relationship with the counterparty. The following analysis provides quantitative information regarding these risks.

Interest Rate Sensitivity

Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2024, we had cash and cash equivalents of $17.5 million, restricted cash of $10.0 million, and short-term securities of $44.8 million. We generally hold our cash in interest-bearing demand deposit accounts and short-term securities. Due to the nature of our cash and investment portfolio, a hypothetical 100 basis point change in interest rates would not have a material effect on the fair value of our cash. Our cash is held for working capital purposes. We purchase treasury bills and money-market funds which are rated by nationally recognized statistical credit rating organizations in accordance with its investment policy. This policy is designed to minimize our exposure to credit losses and to ensure that the adequate liquidity is maintained at all times to meet anticipated cash flow needs.

As of December 31, 2024, we had $0.4 million in convertible promissory notes, which was comprised of non-interest-bearing borrowings under the 2018 and 2020 Convertible Notes. Based on the principal amounts of the convertible promissory notes and the interest rate assigned to the convertible promissory notes, an immediate 10% change in interest rates would not have a material impact on our convertible promissory notes, financial position or results of operations.

Foreign Currency Exchange Risk

Our reporting and functional currency is the U.S. dollar, and the functional currency of our foreign subsidiaries is generally the respective local currency. The assets and liabilities of each of our foreign subsidiaries are translated into U.S. dollars at exchange rates in effect at each balance sheet date. Adjustments resulting from translating foreign functional currency financial statements into U.S. dollars are recorded as a separate component on the consolidated statements of comprehensive loss. Equity transactions are translated using historical exchange rates. Expenses are translated using the average exchange rate during the previous month. Gains or losses due to transactions in foreign currencies are included in interest and other income, net in our consolidated statements of operations.

The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in foreign exchange gains and losses related to changes in foreign currency exchange rates. In the event our foreign currency denominated assets, liabilities, revenue, or expenses increase, our results of operations may be more greatly affected by fluctuations in the exchange rates of the currencies in which we do business, resulting in unrealized foreign exchange gains or losses. We have not engaged in the hedging of foreign currency transactions to date, although we may choose to do so in the future. No strategy can completely insulate us from risks associated with such fluctuations and our currency exchange rate risk management activities could expose us to substantial losses if such rates move materially differently from our expectations.

A hypothetical 10% change in the relative value of the U.S. dollar to other currencies during any of the periods presented would not have had a material effect on our consolidated financial statements, but could result in significant unrealized foreign exchange gains or losses for any given period.

Item 8. Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the shareholders and the Board of Directors of ATAI Life Sciences N.V.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ATAI Life Sciences N.V. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey
March 17, 2025

We have served as the Company's auditor since 2020.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 17,505	$ 45,034
Securities carried at fair value	44,825	109,223
Short-term restricted cash for other investments	10,000	—
Committed investment funds	—	25,000
Prepaid expenses and other current assets	7,795	5,830
Short-term notes receivable - related party, net	—	505
Total current assets	80,125	185,592
Property and equipment, net	2,535	981
Operating lease right-of-use assets, net	1,334	1,223
Other investments held at fair value	28,887	89,825
Other investments	42,079	1,838
Intangible assets, net	3,246	1,772
Goodwill	331	—
Long-term notes receivable - related party, net	—	97
Convertible notes receivable - related party	—	11,202
Other assets	850	948
Total assets	$ 159,387	$ 293,478
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,616	$ 4,589
Accrued liabilities	9,847	15,256
Current portion of lease liabilities	477	275
Short-term convertible promissory notes and derivative liability - related party	1,150	—
Short-term convertible promissory notes and derivative liability	1,840	—
Current portion of long-term debt	6,374	—
Other current liabilities	2,647	—
Total current liabilities	24,951	20,120
Contingent consideration liability - related party	110	620
Contingent consideration liabilities	212	1,637
Noncurrent portion of lease liabilities	732	990
Convertible promissory notes and derivative liability - related party	—	164
Convertible promissory notes and derivative liability	—	2,666
Long-term debt, net	14,133	15,047
Other liabilities	2,695	7,918
Total liabilities	$ 42,833	$ 49,162
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Common stock, €0.10 par value ($0.10 and $0.12 par value at December 31, 2024 and December 31, 2023, respectively); 750,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 167,959,752 and 166,026,396 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	18,785	18,573
Additional paid-in capital	816,185	794,787
Accumulated other comprehensive loss	(18,466)	(19,460)
Accumulated deficit	(700,207)	(550,938)
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	116,297	242,962
Noncontrolling interests	257	1,354
Total stockholders' equity	116,554	244,316
Total liabilities and stockholders' equity	$ 159,387	$ 293,478

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2024	2023
License revenue	$ 308	$ 314
Operating expenses:		
Research and development	55,455	62,203
General and administrative	47,544	63,582
Total operating expenses	102,999	125,785
Loss from operations	(102,691)	(125,471)
Other income (expense), net:		
Interest income	778	1,847
Interest expense	(3,124)	(2,656)
Benefit from research and development tax credit	525	2,445
Change in fair value of assets and liabilities, net	(48,879)	86,583
Gain on settlement of pre-existing contract	5,567	—
Impairment of other investments	—	(1,011)
Gain on deconsolidation of a variable interest entity, net	—	60
Gain on dissolution of a variable interest entity	1,166	—
Foreign exchange loss, net	(1,263)	(894)
Other income (expense), net	(484)	(189)
Total other income (expense), net	(45,714)	86,185
Net loss before income taxes	(148,405)	(39,286)
Benefit from (provision for) income taxes	356	(1,016)
Losses from investments in equity method investees, net of tax	(2,000)	(3,593)
Net loss	(150,049)	(43,895)
Net loss attributable to noncontrolling interests	(780)	(3,671)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (149,269)	$ (40,224)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.93)	$ (0.25)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	160,159,983	158,833,785

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	For the year ended December 31,	
	2024	2023
Net loss	$ (150,049)	$ (43,895)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	994	2,242
Comprehensive loss	$ (149,055)	$ (41,653)
Net loss attributable to noncontrolling interests	(780)	(3,671)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests	32	(1)
Comprehensive loss attributable to noncontrolling interests	(748)	(3,672)
Comprehensive loss attributable to ATAI Life Sciences N.V. stockholders	$ (148,307)	$ (37,981)

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional	Share	Accumulated Other		Total Stockholders' Equity Attributable to ATAI Life Sciences		Total
	Shares	Amount	Paid-In Capital	Subscriptions Receivable	Comprehensive Loss	Accumulated Deficit	N.V. Stockholders	Noncontrolling Interests	Stockholders' Equity
Balances at December 31, 2022	165,935,914	$ 18,562	$ 774,092	$ (24)	$ (21,702)	$ (510,188)	$ 260,740	$ 5,026	$ 265,766
Issuance of shares upon exercise of stock options	74,562	9	172	—	—	—	181	—	181
Settlement of issuance of shares upon exercise of stock options	—	—	—	24	—	—	24	—	24
Issuance of shares upon note conversion	15,920	2	18	—	—	—	20	—	20
Adjustment to additional paid in capital upon consolidation of variable interest entity, net	—	—	(10,809)	—	—	—	(10,809)	—	(10,809)
Adjustment to additional paid in capital upon debt modification	—	—	(1,668)	—	—	—	(1,668)	—	(1,668)
Adjustment to accumulated deficit (pursuant to adoption of ASU 2016-13)	—	—	—	—	—	(526)	(526)	—	(526)
Stock-based compensation expense	—	—	32,982	—	—	—	32,982	—	32,982
Foreign currency translation adjustment, net of tax	—	—	—	—	2,242	—	2,242	(1)	2,241
Net loss	—	—	—	—	—	(40,224)	(40,224)	(3,671)	(43,895)
Balances at December 31, 2023	166,026,396	18,573	794,787	—	(19,460)	(550,938)	242,962	1,354	244,316
Issuance of shares upon exercise of stock options	453,043	49	485	—	—	—	534	—	534
Issuance of shares upon restricted stock units vest	1,480,313	163	(163)	—	—	—	—	—	—
Adjustment to additional paid in capital upon acquiring additional interest in variable interest entity	—	—	(115)	—	—	—	(115)	—	(115)
Adjustment to additional paid in capital upon debt modification	—	—	(3,590)	—	—	—	(3,590)	—	(3,590)
Adjustment to additional paid in capital upon dissolution of variable interest entity	—	—	(709)	—	—	—	(709)	(349)	(1,058)
Stock-based compensation expense	—	—	25,490	—	—	—	25,490	—	25,490
Foreign currency translation adjustment, net of tax	—	—	—	—	994	—	994	32	1,026
Net loss	—	—	—	—	—	(149,269)	(149,269)	(780)	(150,049)
Balances at December 31, 2024	167,959,752	$ 18,785	$ 816,185	$ —	$ (18,466)	$ (700,207)	$ 116,297	$ 257	$ 116,554

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the year ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (150,049)	$ (43,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of long-term assets	473	319
Noncash lease expense	416	383
Amortization of debt discount	515	371
Stock-based compensation expense	25,490	32,982
Noncash change in the fair value of assets and liabilities, net	51,579	(86,583)
Loss on sale of investment held at fair value	2,075	—
Gain on dissolution of a variable interest entity	(1,166)	—
Gain on settlement of pre-existing contract	(5,567)	—
Impairment of intangible assets	919	—
Gain on deconsolidation of a variable interest entity, net	—	(60)
Impairment of other investments	—	1,011
Unrealized foreign exchange loss, net	1,078	799
Losses from investments in equity method investees, net of tax	2,000	3,593
Other income (expense), net	(1,000)	(507)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,091)	8,663
Accounts payable	(1,872)	2,138
Accrued liabilities and other liabilities	(6,237)	(3,332)
Net cash used in operating activities	(82,437)	(84,118)
Cash flows from investing activities		
Proceeds from sale and maturities of securities carried at fair value	65,560	138,983
Proceeds from sale of other investment held at fair value	16,093	—
Cash received in acquisition of IntelGenx Corp.	359	—
Cash paid for securities carried at fair value	—	(160,262)
Cash paid for investments	(15,000)	(25,000)
Cash paid for short-term notes receivable - related party	(5,745)	—
Cash paid for short-term convertible notes receivable and warrant - related party	(2,000)	—
Cash paid for intangible asset	(83)	—
Cash paid for long-term notes receivable - related parties, net	—	(3,500)
Cash paid for convertible notes receivable - related party	—	(2,014)
Cash paid for other investments held at fair value	—	(956)
Proceeds from sale of other investment	—	486
Cash paid for capitalized internal-use software development costs	(6)	(331)
Cash paid out in variable interest entity deconsolidation	—	(443)
Cash paid for property and equipment	(6)	(259)
Net cash provided by (used in) investing activities	59,172	(53,295)
Cash flows from financing activities		
Proceeds from debt financing	5,000	—
Proceeds from issuance of shares upon exercise of stock options	535	205
Proceeds from conversion of convertible notes to common stock	—	20
Cash paid for acquisition of noncontrolling interest	—	(8,480)
Financing costs paid	(161)	(100)
Net cash provided by (used in) financing activities	5,374	(8,355)
Effect of foreign exchange rate changes on cash	362	189
Net decrease in cash, cash equivalents and restricted cash	(17,529)	(145,579)
Cash, cash equivalents and restricted cash – beginning of the period	45,034	190,613
Cash, cash equivalents and restricted cash – end of the period	$ 27,505	$ 45,034
Supplemental disclosures:		
Cash paid for interest	$ 2,159	$ 1,923
Cash paid for taxes	$ 411	$ 1,475
Supplemental disclosures of noncash investing and financing information:		
Discharge of notes receivable	$ 5,356	$ —
Noncash exchange of convertible promissory note modification	$ 3,586	$ 1,668
Noncash consideration for acquisition of noncontrolling interest, net	$ —	$ 2,315
Noncash receipt of call option	$ —	$ (5,062)
Noncash deferred credit	$ —	$ 5,062
Right of use asset obtained in exchange for operating lease liabilities	$ —	$ 1,377
Noncash consideration for variable interest deconsolidation	$ 115	$ —

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

ATAI Life Sciences N.V. (“atai”, "Company"), headquartered in Berlin, Germany is the parent company of ATAI Life Sciences AG and, along with its subsidiaries, is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. Founded in 2018, atai emerged from the urgent need for better mental health solutions for patients who are under-served by current treatment options. The Company is advancing a pipeline of interventional psychiatric product candidates designed to address the complex nature of mental health disorders. The Company believes that these investigational compounds have the potential to become fast-acting, durable, and commercially scalable therapies for mental health patients in need of new treatment options.

The Company's research is focused on developing rapid-acting, effective and durable mental health treatments that can deliver large-scale patient impact. The Company is committed to leading a new era of mental health treatment – one that not only offers relief from symptoms, but the possibility of an improved quality of life and lasting change. The Company pursues this in two ways: the Company develops novel product candidates in-house and the Company makes strategic investments in companies developing promising product candidates.

The Company has built a diversified pipeline of drug and discovery development programs, including psychedelic and nonpsychedelic compounds. Psychedelics are emerging as novel therapies for mental health disorders, such as depression and, with growing scientific support, recent regulatory advancements and increasing patient and physician acceptance. There is a growing body of clinical evidence that supports the development of psychedelics, which the Company believes may have potential therapeutic benefits, such as a rapid onset of effect and sustained efficacy after a short-course of administration. The Company believes these programs, which include new molecular entities as well as variants of known compounds with unique pharmacology, have the potential to address unmet needs in mental health disorders.

These programs vary across stage of development, targeted indication and proposed mechanism of action, which the Company believes will improve the commercial potential and risk profile of our pipeline in the aggregate. The Company also prioritizes the development of, and investments in companies who are developing, compounds and compound classes that have shown potential for efficacy and safety in prior clinical trials or observational studies.

The Company is subject to risks and uncertainties common to clinical stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, third-party clinical research organizations and manufacturers, protection of proprietary intellectual property and technology, compliance with government regulations and the ability to secure additional capital to fund operations. Therapeutic candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s therapeutic development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from sales.

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2024, the Company had cash and cash equivalents of $17.5 million, restricted cash of $10.0 million, and short-term securities of $44.8 million and its accumulated deficit was $700.2 million. The Company has historically financed its operations through the sale of equity securities, sale of convertible notes, debt financings, and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates.

2. Basis of Presentation, Consolidation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and follow the requirements of the United States Securities and Exchange Commission ("SEC"), and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position, results of operations and comprehensive loss, and cash flows for the periods presented.

Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU") issued by the Financial Accounting Standards Board ("FASB").

Reclassifications

Certain reclassifications were made to prior period amounts in the consolidated financial statements and accompanying notes to conform with current year presentation due to the increase in the balances of the Company's intangible assets during the period.

Consolidation

The Company's consolidated financial statements include the accounts of atai and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation. The Company's reporting currency is the U.S. dollar.

The Company's policy is to consolidate all entities that it controls by ownership of a majority of the outstanding voting stock. In addition, entities that meet the definition of a variable interest entity ("VIE") for which atai is the primary beneficiary are consolidated. The primary beneficiary is the party who has the power to direct the activities of a VIE that most significantly impact the entity's economic performance and who has an obligation to absorb losses of the entity as well as a right to receive benefits from the entity that could potentially be significant to the entity. For consolidated entities that are less than wholly-owned, the third-party's holding of equity interest is presented as Noncontrolling interests in the Company's consolidated balance sheets and consolidated statements of stockholders' equity. The portion of net earnings attributable to the noncontrolling interests is presented as Net loss attributable to noncontrolling interests in the Company's consolidated statements of operations.

Ownership interests in entities over which the Company has significant influence, but not a controlling financial interest, are accounted for under either the alternative measurement under ASC 321 or as an equity method investment. Investments eligible for the measurement alternative under ASC 321 are carried at its initial cost, with remeasurements to fair value upon impairment or upon a price change observed in an orderly transaction of the same or similar investment of the same issuer. For equity method investments where the Company has not elected the fair value option, it records gains (losses) from investments in equity method investees, net of tax, for its proportionate share of the underlying company's net results until the investment balance is adjusted to zero. If the Company makes subsequent additional investments in that same company, it may record additional gains (losses) based on changes to its investment basis and also may record additional income (loss) in equity method investments. If the Company has elected the fair value option for an equity investment, the fair value of the investment will be recorded upon acquisition and any changes in fair value will be recorded as a component of other income (expense), net.

Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to the fair value of securities carried at fair value, the fair value of other investments held at fair value, the fair value of convertible notes receivable, definite-lived intangible assets, accruals for research and development costs, the fair value of contingent consideration liabilities, the fair value of assets acquired and liabilities assumed in acquisitions, noncontrolling interests recognized in acquisitions, revenue recognition, the valuation of stock-based awards, impairment of long-lived assets, including goodwill, income taxes, including uncertain tax positions, and the valuation allowance of deferred tax assets.

The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. The Company's cash is mainly held in financial institutions in the United States. Amounts on

deposit may at times exceed federally insured limits. The Company does not believe that it is exposed to any significant credit risk related to these instruments.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2024 and 2023, cash and cash equivalents consisted of cash on deposit and cash held in high-yield savings accounts and money market funds, and at times in excess of federally insured limits.

Investment Securities Portfolio

The Company maintains an investment portfolio, which is comprised of money market funds and U.S. treasury securities as well as corporate notes and bonds and U.S. government agencies in the prior year. The Company classified securities in the investment portfolio as available-for-sale securities. Furthermore, the Company elected the fair value option for the available-for-sale securities in the investment portfolio. The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument-by-instrument basis and applied to an entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a Change in fair value of assets and liabilities, net on the consolidated statements of operations and the amortized cost of investments approximates their fair value. The Company's securities in the investment portfolio will mature within one year.

Accounts Receivable

The Company's accounts receivable relate to licensing and collaboration agreements, including agreements for product development, licensing, and supply agreements assumed through its acquisition of IntelGenx Corp. ("IGX") in October 2024 as well as for the Company's licensing agreement with Otsuka, and services performed on behalf of non-consolidated VIEs (defined below). These accounts receivable are short-term in nature. The Company estimates expected credit losses over the life of the financial assets as of the reporting date based on relevant information about past events, current conditions, and reasonable and supportable forecasts. For the years ended December 31, 2024 and 2023, the Company recognized its accounts receivable in Other current assets within its consolidated balance sheets. For the years ended December 31, 2024 and 2023, the Company had no allowance for credit losses.

Property and Equipment

The Company's property and equipment consists of manufacturing equipment, laboratory and office equipment, furniture and fixtures, and computer equipment and is recorded at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation of property and equipment is recorded using the straight-line method over the estimated useful lives of the related assets once the asset has been placed in service. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter. The Company estimates useful lives by asset class based on the below useful lives:

Asset	Estimated useful lives used
Manufacturing equipment	5 to 20 years
Laboratory and office equipment	5 to 10 years
Furniture and fixtures	7 years
Computer equipment	5 years

Leases

The Company accounts for its leases in accordance with Accounting Standards Codification (“ASC”) Topic 842, *Leases* ("ASC 842"). At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease based on the unique facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease the Company (i) identifies lease and non-lease components, (ii) determines the consideration in the contract, (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease right-of-use (ROU) assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. For lease arrangements with an initial term of 12 months or less, the Company does not recognize a lease liability and ROU asset; instead, the Company recognizes the related lease payments as lease expense on a straight-line basis over the lease term.

The Company, through its various subsidiaries, are lessees for several leases designated as operating leases under ASC 842. The Company presents operating leases on the consolidated balance sheets within Operating lease right-of-use assets, net, Current portion of lease

liabilities, and Noncurrent portion of lease liabilities. On the consolidated statements of operations, the Company presents amortization of operating leases as lease expense within Research and development expenses or General and administrative based on operating lease use.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. The Company does not include any of these options within the expected lease term, as it is not reasonably certain it will exercise these options.

Intangible Assets

The Company has definite-lived intangible assets that are amortized on a straight-line basis over the period in which the Company expects to receive economic benefit and are reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. The determination of the expected life will be dependent upon the use and underlying characteristics of the intangible asset. In the Company's evaluation of the intangible assets, it considers the term of the underlying asset life and potential limitations to its useful life, including any legal, regulatory, contractual, or economic factors.

The Company also owns certain developed and acquired in-process research and development ("IPR&D") intangible assets. These IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. These IPR&D assets are not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. Acquired IPR&D pursuant to an asset acquisition that has no alternative future use is expensed immediately as a component of Research and development expense in the consolidated statements of operations.

The Company presents definite- and indefinite-lived intangible assets on the consolidated balance sheets within Intangible assets, net. On the consolidated statements of operations, the Company presents amortization of definite-lived intangible assets as amortization expense within General and administrative or Research and development based on intangible asset use.

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired.

Business Combinations

The Company evaluates each of its acquisitions under the accounting framework in Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*, to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, the Company first performs a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquired set is a business.

The Company accounts for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. The Company's estimates of fair value are based upon assumptions believed to be reasonable, but these assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill.

During the measurement period, which may be up to one year from the acquisition date, the Company adjusts the provisional amounts of assets acquired and liabilities assumed with the corresponding offset to goodwill to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded within the Company's consolidated statements of operations.

The Company allocates the purchase price of acquired entities to the underlying tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values, with any excess recorded as goodwill. The valuations of the acquired assets and liabilities will impact the determination of future operating results. Determining the fair value of assets the Company acquires and liabilities assumed requires management's judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, discount rates, asset lives and market multiples, among other items. The Company determines the fair values of intangible assets acquired generally in consultation with third-party valuation advisors. Fair value adjustments to the assets and liabilities are recognized and the results of operations of the acquired business are included in the Company's consolidated financial statements from the effective date of the acquisition. For the year ended December 31, 2024, the Company completed a transaction that was accounted for as a business combination. The Company did not have any acquisitions that were accounted for as business combinations for the year ended December 31, 2023.

If the Company's screen test determines the fair value of gross assets acquired is concentrated into a single identifiable asset, and the Company is the primary beneficiary, the transactions are accounted for under ASC 810, *Consolidation*, and no goodwill is recognized. Rather, the Company recognizes the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE was a business and subject to the guidance on recognition and measurement in a business combination under ASC 805, and recognizes a gain or loss for the difference between (a) the sum of the fair values of consideration paid (including any contingent consideration) and noncontrolling interests, (b) the fair value of the VIE's identifiable assets and liabilities, and (c) the reported amounts of any previously held interests. Acquisition-related expenses incurred by the Company in asset acquisitions that involve the initial consolidation of a VIE that is not a business, are not included as a component of consideration transferred, but are accounted for as an expense in the period in which the costs are incurred. In an asset acquisition, including the initial consolidation of a VIE that is not a business, acquired IPR&D with no alternative future use is expensed immediately as a component of in-process research and development expense in the consolidated statements of operations and comprehensive loss.

Variable Interest Entities and Voting Interest Entities

The Company consolidates those entities in which it has a direct or indirect controlling financial interest based on either the variable interest model (the "VIE model") or the voting interest model (the "VOE model") as prescribed under ASC 810, *Consolidation*.

VIEs are entities that, by design, either (i) lack sufficient equity to permit the entity to finance its activities without additional subordinated financial support from other parties; or (ii) have equity investors that do not have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The primary beneficiary of a VIE is required to consolidate the assets and liabilities of the VIE. The primary beneficiary is the party that has both (i) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance; and (ii) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE through its interest in the VIE.

To assess whether the Company has the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, the Company considers all the facts and circumstances, including its role in establishing the VIE and its ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the board of directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether the Company has the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, the Company considers all of its economic interests, which primarily include equity investments in preferred and common stock and notes receivable that are convertible into preferred stock, that are deemed to be variable interests in the VIE. This assessment requires the Company to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. Factors considered in assessing the significance include: the design of the VIE, including its capitalization structure; subordination of interests; payment priority; relative share of interests held across various classes within the VIE's capital structure; and the reasons why the interests are held by the Company.

At the VIE's inception, the Company determines whether it is the primary beneficiary and if the VIE should be consolidated based on the facts and circumstances. The Company then performs on-going reassessments of the VIE based on reconsideration events and reevaluates whether a change to the consolidation conclusion is required each reporting period. If the Company is not deemed to be the primary beneficiary in a VIE, the Company accounts for the investment or other variable interests in a VIE in accordance with the applicable GAAP.

Upon the occurrence of certain events and on a regular basis, the Company evaluates whether it no longer has a controlling interest in its consolidated VIEs. If the Company determines it no longer has a controlling interest, the subsidiary is deconsolidated. The Company records a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in the former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

Entities that do not qualify as a VIE are assessed for consolidation under the VOE model. Under the VOE model, the Company consolidates the entity if it determines that it, directly or indirectly, has greater than 50% of the voting shares and that other equity holders do not have substantive voting, participating or liquidation rights.

Other Investments Held at Fair Value

Prior to the Company's acquisition of IGX in October 2024, as permitted under Accounting Standards Codification 825, *Financial Instruments ("ASC 825")*, the Company elected the fair value option to account for its investment in IntelGenx, which otherwise would have been subject to ASC 323. In accordance with ASC 825, the Company recorded this investment at fair value under the Other

investments held at fair value in the Company's consolidated balance sheets and changes in the fair value are recognized as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

In January 2024, the Company received Additional Warrants (defined in Note 5) pursuant to the Beckley subscription and shareholders' agreement. The Company determined that the Additional Warrants meet the definition of a derivative instrument under Accounting Standards Codification 815, *Derivatives and Hedging*, and recorded the additional Warrants under the Other investments held at fair value in the consolidated balance sheets, with subsequent changes in fair value being reflected through the consolidated statements of operations in the Change in fair value of assets and liabilities, net.

As of August 2023, the Company evaluated its ability to continue to exercise significant influence over its investment in Compass and determined that it no longer had significant influence. The Company's COMPASS investment is accounted for at fair value under Accounting Standards Codification 321, *Investments-Equity Securities* ("ASC 321") and recorded in Other investments held at fair value on the consolidated balance sheets and changes in fair value are recognized as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

Other Investments

The Company holds investments in various equity securities that do not have a readily available fair value. The Company records these investments under either the alternative measurement under ASC 321 or as an equity method investment within Other investments on the Company's consolidated balance sheets.

Alternative Measurement

Other investments include ownership rights that either (i) do not provide the Company with control or significant influence, or (ii) do not have risk and reward characteristics that are substantially similar to an investment in the investee’s common stock. The Company records such investments under the measurement alternative method pursuant to ASC 321 as these investments do not have readily determinable fair values. Under the measurement alternative method, the Company records the investment at cost less impairment losses, if any, unless it identifies observable price changes in orderly transactions for the identical or a similar investment of the same issuer, in which case the Company will measure its investments at fair value as of the date that the observable transaction occurred. Such investments are presented as Other Investments on the consolidated balance sheets and any impairment recognized related to these investments are presented as Impairment of other investments, a component of other income (expense), net in the consolidated statements of operations.

The Company performs a qualitative assessment at each reporting period considering impairment indicators to evaluate whether the investment is impaired. Impairment indicators that the Company considers include but are not limited to; i) a significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee, ii) a significant adverse change in the regulatory, economic, or technological environment of the investee, iii) a significant adverse change in the general market condition of either the geographical area or the industry in which the investee operates, iv) a bona fide offer to purchase, an offer by the investee to sell, or a completed auction process for the same or similar investment for an amount less than the carrying amount of that investment; v) factors that raise significant concerns about the investee’s ability to continue as a going concern, such as negative cash flows from operations, working capital deficiencies, or noncompliance with statutory capital requirements or debt covenants. If the qualitative assessment indicates that an investment is impaired, a loss is recorded equal to the difference between the fair value and carrying value of the investment.

Equity Method Investments

The Company utilizes the equity method to account for investments when it possesses the ability to exercise significant influence, but not control, over the operating and financial decisions of the investee. Generally, the ability to exercise significant influence is presumed when the investor possesses more than 20% of the voting interests of the investee. This presumption may be overcome based on specific facts and circumstances that demonstrate that the ability to exercise significant influence is not present. The Company applies the equity method to investments in common stock and to other investments in nonconsolidated entities that have risk and reward characteristics that are substantially similar to an investment in the investee’s common stock.

In applying the equity method, the Company’s investments are initially recorded at cost in Other investments on the consolidated balance sheets. Upon recording an equity method investment, the Company evaluates whether there are basis differences between the carrying value and fair value of the Company’s proportionate share of the investee’s underlying net assets. Typically, the Company amortizes basis differences identified on a straight-line basis over the underlying assets’ estimated useful lives when calculating the attributable earnings or losses, excluding the basis differences attributable to IPR&D that had no alternative future use. To the extent a basis difference relates to IPR&D and the investee is not a business as defined in ASC 805, the Company immediately expenses such basis difference related to IPR&D. If the Company is unable to attribute all the basis difference to specific assets or liabilities of the investee, the residual excess of the cost of the investment over the proportional fair value of the investee’s assets and liabilities is recognized within the equity investment balance.

The Company subsequently adjusts the carrying amount of the investment by the Company’s proportionate share of the net earnings or losses and other comprehensive income or loss of the investee based on the Company’s percentage of common stock or in-substance common stock ownership during the respective reporting period. The Company records its share of the results of equity method investees

and any impairment related to equity method investments as earnings or losses from investments in equity method investees, net of tax in the consolidated statements of operations. In the event that net losses of the investee reduce the carrying amount to zero, additional net losses may be recorded if the Company has other investment or other outstanding loans and advances to the investee and would be determined based on the Company's proportionate share of the respective class of securities

Currently the Company is not obligated to make additional capital contributions for its equity method investments, and therefore only records losses up to the amount of its total investment, inclusive of other investments in and loans to the investee, which are not accounted for as equity method investments. To the extent that the Company's share of losses of the equity method investee on a cumulative basis exceeds its total investment amount, inclusive of its equity method investment, other investments, and loans, the Company will discontinue equity method loss recognition as the Company does not have guaranteed obligations of the investee nor has the Company otherwise committed to provide further financial support for the investee. The Company will resume recording its share of losses in future periods only after its share of the earnings of the equity method investee equals the Company's share of losses not recognized during the suspended period. The Company evaluates additional equity method investments made after the suspension of loss recognition to determine whether such investments represent the funding of prior suspended losses of the equity method investee.

Equity method investments are reviewed for indicators of other-than-temporary impairment at each reporting period. Equity method investments are written down to fair value if there is evidence of a loss in value that is other-than-temporary. Methodologies that the Company may use to estimate the fair value of its equity method investments include, but are not limited to, considering recent investee equity transactions, discounted cash flow analysis, recent operating results, comparable public company operating cash flow multiples and in certain situations, balance sheet liquidation values. If the fair value of the investment has declined below the carrying amount, management considers several factors when determining whether an other-than-temporary decline has occurred, such as the length of the time and the extent to which the estimated fair value or market value has been below the carrying value, the financial condition and the near-term prospects of the investee, the intent and ability of the Company to retain its investment in the investee for a period of time sufficient to allow for any anticipated recovery in market value and general market conditions. The estimation of fair value and whether an other-than-temporary impairment has occurred requires the application of significant judgment and future results may vary from current assumptions. If declines in the value of the equity method investments are determined to be other-than-temporary, a loss is recorded in earnings in the current period as a component of losses from investments in equity method investees, net of tax on the consolidated statements of operations. Evidence of a loss in value might include, but would not necessarily be limited to, absence of an ability to recover the carrying amount of the investment or inability of the investee to sustain an earnings capacity that would justify the carrying amount of the investment. This evaluation consists of several qualitative and quantitative factors including recent financial results and operating trends of the investee, implied values in recent transactions of investee securities, or other publicly available information that may affect the value of the Company's investments. The Company presents income/losses from equity investments and any impairment related to equity method investments as Income (losses) from investments in equity method investees, net of tax on the consolidated statements of operations.

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful lives of its long-lived assets, including goodwill, identifiable intangible assets subject to amortization, and property plant and equipment, may warrant revision or that the carrying value of the assets may be impaired. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheets. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss in the statements of operations if the carrying value of the intangible asset exceeds its fair value. Fair value is generally estimated based on either appraised value or other valuation techniques. Events that could result in an impairment, or trigger an interim impairment assessment, may include actions by regulatory authorities with respect to the Company or its competitors, new or better products entering the market, changes in market share or market pricing, changes in the economic lives of the assets, changes in the legal framework covering patents, rights or licenses, and other market changes which could have a negative effect on cash flows and which could result in an impairment. For the year ended December 31, 2024, the Company recognized impairment charges for certain indefinite-lived intangible assets. Refer to Note 10 for more information. The Company did not recognize impairment charges for any of their long-lived assets for the year ended December 31, 2023.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of the reporting unit exceeds the fair value of the reporting unit, in accordance with Other (Topic 350): Simplifying the Accounting for Goodwill Impairment. Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASC 350. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

Changes in these assumptions and resulting valuations could result in future long-lived asset impairment charges. Management will continue to monitor any changes in circumstances for indicators of impairment. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

Convertible Notes Receivable

Prior to the Company's acquisition of IGX in October 2024, as permitted under ASC 825, *Financial Instruments*, or ASC 825, the Company elected the fair value option to account for its IntelGenx convertible notes, which otherwise would have been subject to ASC 320. In accordance with ASC 825, the Company recorded this investment at fair value under Convertible notes receivable - related party in the Company's consolidated balance sheets and changes in fair value are recognized as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

Notes Receivable

Prior to the Company's acquisition of IGX in October 2024, the Company had certain notes receivable that were carried at cost, which included the principal value of the note receivable, accrued interest and net of any payments received and expected credit losses. Management utilized an undiscounted probability-of-default ("PD") and loss-given-default ("LGD") method for estimating credit losses on its assets pool, which was comprised of loans to other companies. Under the PD and LGD method, the expected credit loss percentage (or "loss rate") is calculated as the probability of default (i.e., the probability the asset will default within the given time frame) multiplied by the loss given default (i.e., the percentage of the asset not expected to be collected because of default).

For the year ended December 31, 2024, the notes receivable balance was zero. For the year ended December 31, 2023, based on the terms of the notes receivable, certain notes receivable were classified as long-term as their payments were due after twelve months from the balance sheet date.

Contingent Consideration Liabilities

The Company may record contingent consideration as part of the cost of acquisitions. Contingent consideration is recognized at fair value as of the date of acquisition and accounted under Contingent consideration liabilities or Contingent consideration liability - related party on the consolidated balance sheets. Contingent considerations are remeasured on a quarterly basis, as appropriate, using a discounted cash-flow valuation technique until fulfillment of the contingency. Changes in the fair value of the contingent consideration are recognized as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

Debt Issuance Costs and Debt Discount

Debt issuance costs include incremental and direct costs incurred in relation to debt, such as legal fees, accounting fees, and other direct costs of the financing. Amounts paid to the lender are a reduction in the proceeds received by the Company and are generally considered a component of issuance discount, unless it is paid to compensate the lender for the services rendered or as a reimbursement of direct costs incurred by them in relation to the debt, in which case it would be akin to a debt issuance cost.

Debt issuance costs related to a recognized debt liability are presented in the consolidated balance sheets as a direct deduction from the carrying amount of the debt liability rather than as an asset, consistent with the presentation of debt discounts, and are amortized to interest expense over the term of the related debt using the effective interest method.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development consist of salaries, benefits and other personnel related costs including equity-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on the Company's behalf and allocated facility and other related costs. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

Preclinical and clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development expense.

Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses any litigation or other claims it may confront to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company will accrue for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company will accrue the minimum of the

range. In the cases where the Company believes that a reasonably possible loss exists, the Company will disclose the facts and circumstances of the litigation, including an estimable range, if possible.

Revenue Recognition

The Company accounts for its revenue in accordance with ASC 606, *Revenue Recognition.* ASC 606 outlines a five-step process for recognizing revenue from contracts with customers: i) identify the contract with the customer, ii) identify the performance obligations in the contract, (iii) determine the transaction price, iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Payments received in advance of the Company satisfying performance obligations will be recognized as deferred revenue which is presented within Other current liabilities on the consolidated balance sheets. As noted above, the Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. The Company does recognize revenue through their licenses of intellectual property and manufacturing contracts.

Licenses of Intellectual Property

The Company may enter into collaboration and out-licensing arrangements for research and development, manufacturing, and commercialization activities with counterparties for the development and commercialization of its product candidates. The agreements may have units of account within the scope of ASC 606 where the counterparties meet the definition of a customer as well as units of account within the scope of ASC 808 where both parties are determined to be active participants exposed to significant risk and rewards.

The arrangements may contain multiple components, which may include (i) licenses, or options to obtain licenses to the Company's intellectual property or sale of the Company's license, (ii) research and development activities, (iii) participation on joint steering committees, and (iv) the manufacturing of commercial, clinical or preclinical material. Payments pursuant to these arrangements may include non-refundable, upfront payments, milestone payments upon the achievement of significant development events, research and development reimbursements, sales milestones, and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which the Company enters generally do not include significant financing components.

As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations; b) the transaction price; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price; and d) the measure of progress. The Company uses judgment to determine whether milestones or other variable consideration, except for sales-based milestones and royalties on license arrangements, should be included in the transaction price as described further below.

If a license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from consideration allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other elements, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the counterparties and the availability of its associated expertise in the general marketplace. In addition, the Company considers whether the counterparties can benefit from a promise for its intended purpose without the receipt of the remaining elements, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress as of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, is subject to estimates by management and may change over the course of the arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Customer Options: If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services such as research and development services or manufacturing services, the goods and services underlying the customer options are not considered to be performance obligations at the inception of the arrangement unless a material right is provided to the customer. If the customer option does not represent a material right, the obligation to provide such goods and services is contingent on exercise of the option, and the associated consideration is not included in the transaction price. If a customer option is determined to include a significant and incremental discount and, therefore, represents a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price.

Milestone Payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most-likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For license arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Stock-Based Compensation

The Company accounts for all stock-based payment awards granted to employees, directors and non-employees as stock-based compensation expense based on their grant date fair value. The stock-based payment awards are measured at fair value on the date of the grant and that fair value is recognized as stock-based compensation expense in the Company's consolidated statements of operations over the requisite service period of the respective award. The estimated fair value of awards that contain performance conditions is expensed when the Company concludes that it is probable that the performance condition will be achieved. The Company may grant awards with graded-vesting features. When such awards have only service vesting requirements, the Company elected to record stock-based compensation expense on a straight-line basis. Recognition of compensation cost relating to awards that vest on a "Liquidity Event" (as defined in the award) will be deferred until the consummation of such transaction.

The Company measures the fair value of its stock options that only have service vesting requirements or performance-based options without market conditions using the Black-Scholes option pricing model. For performance-based awards with market conditions, the Company determines the fair value of the awards as of the grant date using a Monte Carlo simulation model.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company's common shares. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the "simplified method" with the continued use of this method extended until such time the Company has sufficient exercise history. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. Because the Company did not have an extended trading history for its common shares, the expected volatility was estimated using weighted average measures of the Company's historical volatility and the historical volatility of a peer group of companies for a period equal to the expected life of the stock options. The Company's peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty. The Company has elected to recognize forfeitures of stock-based compensation awards as they occur.

As part of the valuation of stock-based compensation under the Black-Scholes option pricing model, it is necessary for the Company to use the fair value of its common stock as a valuation input. Prior to the closing of the IPO, the fair value of the Company's common stock was estimated on each grant date. The fair value of the Company's privately held subsidiaries' common stock was also estimated on each grant date. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common stock. The estimation of the fair value of the common stock considered factors including the following: the estimated present value of the Company's future cash flows; the Company's business, financial condition and results of operations; the Company's forecasted operating performance; the illiquid nature of the Company's common stock; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions.

After the closing of the IPO in June 2021, the Company's board of directors determined the fair value of each share of common stock underlying stock-based awards based on the closing price of the Company's common stock as reported by Nasdaq on the date of grant.

Noncontrolling Interests

The Company recognizes noncontrolling interests related to its consolidated VIEs in the consolidated balance sheets as a component of equity, separate from atai stockholders' equity. Changes in the Company's ownership interest in a consolidated VIE that do not result in a loss of control are accounted for as equity transactions. The noncontrolling interests related to its consolidated VIEs are initially recorded at fair value. Net losses in consolidated VIEs are attributed to noncontrolling interests considering the liquidation preferences of the different

classes of equity held by the shareholders in the VIE and their respective interests in the net assets of the consolidated VIE in the event of liquidation, and their pro rata ownership.

In addition, the Company evaluates the classification of noncontrolling interests based upon a review of the legal provisions governing the redemption of such interests as the obligation to redeem these shares are triggered by events that are within the control of the Company. The Company evaluates individual noncontrolling interests for the ability to recognize the noncontrolling interest as permanent equity on the consolidated balance sheets at the time such interests are issued and on a continual basis. Any noncontrolling interest that fails to qualify as permanent equity are considered redeemable noncontrolling interests and reclassified as temporary equity.

The amount of net loss attributable to noncontrolling interests are included in consolidated net loss on the face of the consolidated statements of operations.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to the underpayment of income taxes as a component of the Provision for income taxes in its consolidated statements of operations.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amount reflected in the accompanying consolidated balance sheets for cash and cash equivalents, committed investment funds, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Foreign Currency

Assets and liabilities of foreign operations are translated using exchange rates in effect at the balance sheet date and their results of operations are translated using average exchange rates for the year. Investments accounted for under the equity method and stockholders' equity are translated based on historical exchange rates. Certain transactions of the Company and its subsidiaries are denominated in currencies other than their functional currency. Adjustments resulting from the translation of the financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholders' equity. Foreign exchange transaction gains and losses are recognized as a component of other income (expense), net in the consolidated statements of operations.

Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders for the year by the weighted average number of common stock outstanding during the year. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the year by the weighted average number of common stock, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. The Company uses the treasury stock method to calculate diluted net loss per share. For years in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because their impact would be anti-dilutive to the calculation of net loss per share. For the years ended December 31, 2024 and 2023, the Company reports a combined basic net loss and diluted loss per share of common stock.

Subsequent Events

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were subsequent events that required disclosure or adjustment in these financial statements. See Note 24 to the Company's Consolidated Financial Statements for a discussion of subsequent events.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

ASU 2016-13 Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, Financial Instruments — Credit Losses. This guidance requires immediate recognition of management's estimates of current expected credit losses. Under the prior model, losses were recognized only when losses were deemed probable. The new model is applicable to most financial assets and certain other instruments that are not measured at fair value through net income.

The Company utilizes an undiscounted probability-of-default ("PD") and loss-given-default ("LGD") method for estimating credit losses on its assets pool, which is comprised of loans to other companies. Under the PD and LGD method, the expected credit loss percentage (or "loss rate") is calculated as the probability of default (i.e., the probability the asset will default within the given time frame) multiplied by the loss given default (i.e., the percentage of the asset not expected to be collected because of default). To implement the PD and LGD method, the Company utilizes readily observable market information from term-matched public debt to derive market implied current expected credit losses ("MICECL") grouped by Standard & Poor's ("S&P") credit rating scale. The MICECL framework considers risk characteristics of assets pool based on publicly available or estimated S&P credit ratings to calculate an appropriate credit loss reserve for the pool or group of assets.

ASU 2016-13 requires a cumulative effect adjustment to the statement of financial position as of the beginning of the first reporting period in which it is effective. On January 1, 2023, the Company adopted this guidance and applied a modified-retrospective transition approach through a cumulative-effect adjustment to retained earnings upon adoption. At transition, the new accounting guidance's adoption resulted in an increase to accumulated deficit of $0.5 million, net of tax attributable to an increase in the allowance for credit losses related to its long-term notes receivable - related parties.

Further, the FASB issued ASU 2019-04, ASU 2019-05, ASU 2019-11, ASU 2020-03 and ASU 2022-02 to provide additional clarification and guidance on the credit losses standard. The Company adopted ASU 2019-04, ASU 2019-05, ASU 2019-11, ASU 2020-03 and ASU 2022-02 on January 1, 2023. The adoption of these standards did not have a material impact on the Company's consolidated financial statements or disclosures.

ASU 2023-07 Segment Reporting: Improvements to Reportable Segment Disclosures

In November 2023, the FASB issued new guidance designed to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses per segment. The guidance is effective for all fiscal years beginning after December 15, 2023, and for interim periods beginning after December 15, 2024. The new standard must be adopted on a retrospective basis and early adoption is permitted. The Company adopted this standard for fiscal year 2024, and applied the amendments retrospectively to all prior periods presented in the Company's consolidated financial statements. Refer to Note 23 for more information.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued new guidance designed to improve income tax disclosure requirements, primarily through increased disaggregation disclosures within the effective tax rate reconciliation as well as enhanced disclosures on income taxes paid. The guidance is effective for all fiscal years beginning after December 15, 2024. The new standard can be adopted on a prospective basis with an option to be adopted retrospectively and early adoption is permitted. The Company is not early adopting the standard and is currently evaluating this guidance to determine its impact on the Company's consolidated financial statements.

In November 2024, the FASB issued new guidance designed to improve income statement expense disclosures, primarily by requiring new financial statement disclosures in tabular format and disaggregating information about prescribed categories underlying any relevant income statement captions. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Upon adoption, the new standard may be applied prospectively or retrospectively. The Company is currently evaluating the impact that the adoption may have on its disclosures in its consolidated financial statements.

In November 2024, the FASB issued new guidance which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. The standard is effective for annual periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted for all entities that have adopted the amendments in Update 2020-06. Adoption can be on a prospective or retrospective basis. The Company is currently in the process of evaluating the impact of adoption on the consolidated financial statements.

3. Acquisitions and Dispositions

2024 Acquisitions

IntelGenx Corp.

IntelGenx Technologies Corp. ("IntelGenx") is a novel drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market. In March 2021, IntelGenx and the Company entered into the Strategic Development Agreement and Purchaser Rights Agreement (“PPA”), (described in Note 5). In May 2021, IntelGenx and the Company executed a Securities Purchase Agreement (the “2021 IntelGenx SPA”), (described in Note 5), under which the Company held a 25% voting interest in IntelGenx. Pursuant to the PPA, the Company is entitled to designate a number of directors to the IntelGenx’s board of directors in the same proportion as the shares of common stock held by the Company to the outstanding IntelGenx Common Shares.

The Company and IntelGenx also entered into certain loan agreements and convertible promissory note agreements, including the IntelGenx Term Loan, 2023 Initial Notes, 2023 Subsequent Notes, 2023 Term Loan, and the DIP Loan (as defined and described in Note 6).

In May 2024, IntelGenx announced that its board of directors authorized IntelGenx to bring an application in the Quebec Superior Court to seek protection from creditors under the Companies' Creditors Arrangement Act (“CCAA”) to allow time to review its strategic alternatives. IntelGenx was granted protection pursuant to an initial order ("Initial Order"), which also authorized interim debtor-in-possession financing ("DIP Financing") provided by the Company in order to allow IntelGenx to continue its operations during a restructuring process. Subsequently, IntelGenx obtained approval to implement a sale and investment solicitation process (the "SISP" and the approval, the "SISP Approval Order"). As part of the SISP Approval Order, the Court approved the agreement of a purchase and sale between IntelGenx and the Company, solely for the purpose of constituting the “Stalking Horse Bid" under the SISP. The Stalking Horse Bid established a baseline price and deal structure for the solicitation of superior bids from qualified interested parties.

On September 30, 2024, the Superior Court of Quebec issued an Approval and Vesting Order, sanctioning the transactions contemplated in ATAI’s stalking horse bid, which consisted of the Company acquiring IntelGenx Corp. ("IGX"), the operating company and a subsidiary of IntelGenx Technologies Corp. The acquisition closed on October 2, 2024.

The Company did not exchange any equity or cash in this transaction. Rather, the transaction was structured as a credit bid, which resulted in the Company receiving all issued and outstanding shares of IGX in exchange for the discharge of all senior secured debt payable to the Company by IntelGenx, which included solely the DIP Loan and the IntelGenx Term Loan (described in Note 6). The transaction was further structured to include only the assumption of the assets and liabilities which the Company designated within their Stalking Horse Bid (the “Purchase Transaction”). All remaining unsecured debt payable by IntelGenx, and any remaining assets and liabilities not assumed by the Company in the Purchase Transaction, continue to be held by IntelGenx, and IntelGenx continues to be subject to protections under the CCAA.

The Company continues to hold investments in IntelGenx's common stock, Warrants, and Call Option as well as various notes receivable, as defined and discussed further in Note 5 and Note 6.

The Company determined that the transaction met the definition of a business under ASC 805; therefore, the Company accounted for the transaction as a business combination and applied the acquisition method of accounting. The purchase consideration transferred at the acquisition date was $5.7 million, which was the fair value of the aforementioned discharged senior secured debt. The Company did not include any cash or equity as part of the consideration transferred.

The allocation of the purchase price is based upon certain preliminary valuations and other analyses. As a result, the purchase price amount for the transaction and the allocation of the preliminary purchase consideration are preliminary estimates, and may be subject to change within the measurement period, but no later than one year after the acquisition date.

The following table sets forth the preliminary allocation of the IGX purchase price to the estimated fair value of the net assets acquired at the acquisition date (in thousands):

	Amounts recognized at the Acquisition Date
Assets acquired:	
Cash	$ 359
Accounts receivable	46
Prepaid expenses and other current assets	971
Property and Equipment	1,892
Right-of-use assets, net	527
Definite-lived intangible assets	2,625
Other assets	275
Total assets	$ 6,695
Liabilities assumed:	
Accounts payable	$ 214
Deferred revenue	575
Accrued liabilities	136
Right-of-use liabilities	327
Other current liabilities	59
Total liabilities	$ 1,311
Total identifiable net assets acquired	5,384
Goodwill	331
Total consideration transferred	$ 5,715

IGX results from the acquisition date of October 2, 2024 through December 31, 2024, which are included in the consolidated statements of operations, are as follows (in thousands):

Classification in Consolidated Statements of Operations	Acquisition Date through December 31, 2024
Total revenues	$ 12
Net loss	$ (960)

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the years ended December 31, 2024 and 2023, as if the IGX acquisition had occurred on January 1, 2023. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2023, and is not indicative of what such results would be expected for any future period (in thousands):

	For the year ended December 31,	
	2024	2023
Total revenues	$ 457	$ 501
Net loss	$ (138,803)	$ (50,740)

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and IGX. The summary pro forma financial information primarily reflects the following pro forma adjustments:

- Removal of the acquisition-related transaction fees and costs;
- Removal of any revenue recognized by IGX in connection with services performed for the Company;
- Removal of IGX’s interest expense and the Company's interest income in connection with certain notes receivable instruments;
- Derecognition of any fair value adjustments recognized by the Company for their equity and notes receivable instruments;
- Additional amortization expense from the acquired intangible assets;
- Additional depreciation of fixed assets; and
- Additional lease expense on the ROU assets.

2023 Dispositions

Psyber, Inc.

In October 2023, the Company entered into a Framework Agreement with the founders of Psyber, Inc. ("Founders") through which the Company transferred its equity interest in Psyber, Inc. ("Psyber") to the Founders in exchange for certain intellectual property.

As a result of the disposition, the Company ceased having controlling financial interest in Psyber. The Company determined that it was no longer the primary beneficiary, no longer had the power to direct the significant activities of Psyber, and accordingly, deconsolidated Psyber. The Company derecognized all of Psyber's assets and liabilities, with the exception of the retained intellectual property, from its consolidated balance sheets and recognized a loss of $0.3 million, which was reported as Loss on deconsolidation of a variable interest entity, a component of other income (expense), net in the consolidated statements of operations for the year ended December 31, 2023.

The Company concluded that the decision to deconsolidate Psyber, which was based on resource capital allocation decisions, did not represent a significant strategic shift that would have a material effect on the Company's operations and financial results. Therefore, the Company did not present the results of Psyber prior to deconsolidation as discontinued operations in its consolidated statements of operations for the year ended December 31, 2023.

TryptageniX, Inc.

In December 2023, the Company finalized and entered into a Framework Agreement with CB Therapeutics, Inc. ("CBT") through which the Company transferred its equity interest in TryptageniX Inc. ("TryptageniX") to CBT in exchange for certain intellectual property and an Amended and Restated Development Services and Exclusive License Agreement.

As a result of the disposition, the Company ceased having controlling financial interest in TryptageniX. The Company determined that it was no longer the primary beneficiary, no longer had the power to direct the significant activities of TryptageniX, and accordingly, deconsolidated TryptageniX. The Company derecognized all of TryptageniX's assets and liabilities from its consolidated balance sheets, and recognized a gain of $0.4 million, which was reported as Gain on deconsolidation of a variable interest entity, a component of other income, net in the consolidated statements of operations for the year ended December 31, 2023.

The Company concluded that the decision to deconsolidate TryptageniX, which was based on resource capital allocation decisions, did not represent a significant strategic shift that would have a material effect on the Company's operations and financial results. Therefore, the Company did not present the results of TryptageniX prior to deconsolidation as discontinued operations in its consolidated statements of operations for the year ended December 31, 2023.

4. Variable Interest Entities

Consolidated VIEs

At each reporting period, the Company reassesses whether it remains the primary beneficiary for Variable Interest Entities ("VIEs") consolidated under the VIE model.

The entities consolidated by the Company are comprised of wholly and partially owned entities for which the Company is the primary beneficiary under the VIE model as the Company has (i) the power to direct the activities that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses that could potentially be significant to the VIE, or the right to receive benefits from the VIE that could potentially be significant to the VIE. The results of operations of the consolidated entities are included within the Company's consolidated financial statements from the date of acquisition to December 31, 2024.

As of December 31, 2024 and 2023, the Company has accounted for the following consolidated investments as VIEs:

Consolidated Entities	Relationship as of December, 31, 2024	Relationship as of December 31, 2023	Date Control Obtained	Ownership % December 31, 2024	Ownership % December 31, 2023
Perception Neuroscience Holdings, Inc.	Controlled VIE	Controlled VIE	November 2018	59.2%	59.2%
Recognify Life Sciences, Inc.	Controlled VIE	Controlled VIE	November 2020	51.9%	51.9%

As of December 31, 2024 and 2023, the assets of the consolidated VIEs can only be used to settle the obligations of the respective VIEs. The liabilities of the consolidated VIEs are obligations of the respective VIEs and their creditors have no recourse to the general credit or assets of atai.

Non-Consolidated VIEs as of December 31, 2024

The following investments no longer meet the requirements to consolidate as VIEs as of December 31, 2024:

Kures, Inc.

Kures Inc. ("Kures") was a pre-clinical stage biotech company focusing on developing new opioid-based therapeutics for mood disorders and psychiatry or physical pain using mitragynine and tianeptine derivatives. In August 2019, through a series of transactions, the Company acquired a controlling financial interest in Kures through its purchase of Kures' Series A-1 preferred stock. Immediately following the closing of these transactions, the Company's ownership in Kures was approximately 57.1%. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that Kures was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In July 2024, the Board of Directors for Kures determined it was in the best interests of the company to wind up operations and dissolve Kures through a Plan of Liquidation and Dissolution ("the Plan"). The Plan consisted of several components, including (i) the dissolution of Kures, (ii) transfer of all outstanding shares of Kures Australia Pty Ltd, a wholly owned subsidiary of Kures, to the Company, and (iii) transfer of all clinical trial data relating to the clinical safety and activity of KUR-101 to the Company.

In October 2024, in connection with the dissolution of Kures, Kures and Columbia mutually agreed to terminate the existing License Agreement (the "Termination Agreement"). Under the Termination Agreement, Kures assigned to Columbia all of Kures' intellectual property rights that were filed during the term of the License Agreement and agreed that all licenses granted to Kures by Columbia are terminated. In exchange, Kures received consideration through the relief and discharge of an immaterial amount of outstanding payment obligations due to Columbia.

Immediately prior to the transaction the Company's ownership in Kures was approximately 64.5%. The transaction and dissolution closed in November 2024, with the purchase consideration transferred on the acquisition date of $0.1 million. The Company determined the dissolution of Kures in November 2024 meant the Company no longer held a controlling financial interest, and, therefore, accounted for the dissolution as a deconsolidation of a VIE under ASC 810. The Company derecognized all of Kures's assets and liabilities, with the exception of the retained intellectual property from its consolidated balance sheets and recognized a gain of $1.2 million, which was reported as Gain on dissolution of a variable interest entity, a component of other income (expense), net in the consolidated statements of operations for the year ended December 31, 2024. Pursuant to the Plan, the Company recognized $0.1 million of intellectual property from the transaction within Intangible assets, net on the consolidated balance sheets.

As of December 31, 2023, the Company's ownership in Kures was 64.5% and was a consolidated VIE.

PsyProtix, Inc.

On February 3, 2021, PsyProtix, Inc. ("PsyProtix") was created as a joint venture between the Company and Chymia (the "Founders"), with the intent of PsyProtix becoming a newly formed corporate subsidiary of the Company. PsyProtix was created for the purpose of exploring and developing a metabolomics-based precision psychiatry approach. Based on the Company's assessment of the transaction at the time of

acquisition, the Company concluded that PsyProtix was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In April 2024, the Company and Chymia entered into a Framework Agreement which resulted in the Company's acquisition of Chymia's 25% equity ownership of PsyProtix (the “Stock Transfer”). As a result of the Stock Transfer, the Company owned 100% of the outstanding common stock of PsyProtix, and PsyProtix became a wholly owned subsidiary of the Company. The Stock Transfer was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of Chymia's non-controlling interest and the note receivable forgiven in the acquisition of the additional equity interest was recorded as a reduction in additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

In December 2024, PsyProtix entered into an Agreement and Plan of Merger ("Merger Agreement") with atai Therapeutics Inc., a wholly-owned atai subsidiary. Pursuant to the Merger Agreement, all common stock issued and outstanding of PsyProtix was automatically canceled and retired and ceased to exist. Upon the merger, all assets and liabilities were transferred to atai Therapeutics Inc. and the Company recognized no gain or loss from the transaction in its consolidated statements of operations.

As of December 31, 2023, the Company's ownership in PsyProtix was 75% and was a controlled VIE.

Consolidated VIE Balance Sheets

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all VIEs as of December 31, 2024 (in thousands):

	Perception	Recognify
Assets:		
Current assets:		
Cash	$ 31	$ 819
Accounts receivable	261	—
Prepaid expenses and other current assets	88	40
Total current assets	380	859
Total assets	$ 380	$ 859
Liabilities:		
Current liabilities:		
Accounts payable	$ 276	$ 221
Accrued liabilities	195	961
Other current liabilities	83	4
Total current liabilities	554	1,186
Total liabilities	$ 554	$ 1,186

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all consolidated VIEs as of December 31, 2023 (in thousands):

	Perception	Kures	Recognify	PsyProtix
Assets:				
Current assets:				
Cash	$ 97	$ 257	$ 4,356	$ 35
Accounts receivable	84	—	—	—
Prepaid expenses and other current assets	257	—	450	—
Total current assets	438	257	4,806	35
Long-term notes receivable	—	—	—	97
Other assets	—	—	—	—
Total assets	$ 438	$ 257	$ 4,806	$ 132
Liabilities:				
Current liabilities:				
Accounts payable	$ 31	$ 329	$ 1,926	$ —
Accrued liabilities	718	84	609	26
Other current liabilities	12	—	1	—
Total current liabilities	761	413	2,536	26
Total liabilities	$ 761	$ 413	$ 2,536	$ 26

Non-Consolidated VIEs as of December 31, 2023

The following investments no longer met the requirements to consolidate as VIEs as of December 31, 2023:

EntheogeniX Biosciences, Inc.

In November 2019, the Company entered into a series of agreements with Cyclica Inc. ("Cyclica") to form EntheogeniX Biosciences, Inc. ("EntheogeniX"), a company dedicated to developing the next generation of innovative mental health drugs employing an AI-enabled

computational biophysics platform designed to optimize and accelerate drug discovery. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that EntheogeniX was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In February 2022 and September 2022, the Company purchased additional shares of Class A common stock for an aggregate purchase price of $2.2 million. As a result of anti-dilution protection available to Cyclica, the Company's ownership percentage in EntheogeniX did not change due to its purchase.

In March 2023, the Company purchased additional shares of Class A common stock for an aggregate purchase price of $1.0 million. As a result of anti-dilution protection available to Cyclica, the Company's ownership percentage in EntheogeniX did not change due to its purchase.

In September 2023, the Company and Cyclica entered into a Stock Transfer Agreement which resulted in the Company's acquisition of Cyclica's equity ownership of EntheogeniX for an aggregate purchase price of $0.5 million (the "Stock Transfer"). As a result of the Stock Transfer, the Company owned 100% of the outstanding common stock of EntheogeniX. The Stock Transfer was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of EntheogeniX's noncontrolling interest and the consideration for the acquisition of the additional equity interest was recorded as a reduction in Additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

DemeRx IB, Inc.

In December 2019, DemeRx IB, Inc. ("DemeRx IB") was incorporated as a wholly-owned subsidiary of DemeRx, Inc., formed for the purpose of facilitating a joint venture transaction between DemeRx, Inc. and ATAI AG. DemeRx, Inc. and ATAI AG jointly created DemeRx IB, which was designed to use DemeRx Inc.'s intellectual property to develop Ibogaine as a treatment for opioid dependence. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that DemeRx IB was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.'s equity ownership of DemeRx IB (the "Stock Purchase"). As a result of the Stock Purchase, the Company owned 100% of the outstanding common stock of DemeRx IB. The Stock Purchase consideration included an $8.0 million upfront cash payment, transfer of the Company's ownership in DemeRx, NB, Inc., settlement of a related term loan, and earn-out consideration contingent upon the achievement of certain development milestones directly related to DemeRx's oral capsule formulation of ibogaine ("DMX-1002") program. At the execution of the Stock Transfer, the earn-out consideration was recorded as a liability at an estimated fair value of $1.3 million and reflected in Contingent consideration - related parties in the consolidated balance sheets. The Stock Purchase was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of DemeRx IB's noncontrolling interest and the consideration given for the acquisition of the additional equity interest was recorded as a reduction in Additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

InnarisBio, Inc.

In February 2021, the Company jointly formed InnarisBio, Inc. ("InnarisBio") with UniQuest Pty Ltd ("UniQuest") for the purpose of adding a solgel-based direct-to-brain intranasal drug delivery technology to the Company's platform. Based on the Company's assessment of the transaction at the time of acquisition, the Company concluded that InnarisBio was not a business and accounted for the Company's investment as an initial consolidation of a VIE that is not a business under ASC 810.

In October 2023, InnarisBio and UniQuest entered into an Assignment, Termination and Release Agreement ("ATRA") which resulted in InnarisBio reacquiring UniQuest's equity interest in exchange for the assignment of intellectual property and the termination of certain license and research agreements. The assigned intellectual property has an approximate fair value of $0.1 million, and the termination of agreements resulted in the extinguishment of a $0.1 million contingent commitment liability. As a result of the ATRA, the Company owned 100% of the outstanding common stock of InnarisBio, and InnarisBio became a wholly owned subsidiary of the Company. The ATRA was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of InnarisBio's noncontrolling interest and the consideration given for the acquisition of the additional equity interest was recorded as a reduction in Additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

Noncontrolling Interests

The Company recognizes noncontrolling interests related to its consolidated VIEs and provides a rollforward of the noncontrolling interests balance, as follows (in thousands):

	Perception	Kures	Recognify	Total
Balance as of December 31, 2022	$ 1,731	$ 451	$ 2,844	$ 5,026
Net loss attributable to noncontrolling interests - preferred	(1,302)	(84)	(2,287)	(3,673)
Comprehensive income attributable to noncontrolling interests	(1)	2	—	1
Balance as of December 31, 2023	$ 428	$ 369	$ 557	$ 1,354
Net loss attributable to noncontrolling interests - preferred	(207)	(16)	(557)	(780)
Adjustment to noncontrolling interests upon dissolution of variable interest entity	—	(349)	—	(349)
Comprehensive loss attributable to noncontrolling interests	35	(3)	—	32
Balance as of December 31, 2024	$ 256	$ —	$ —	$ 257

Non-consolidated VIEs

The Company evaluated the nature of its investments in Innoplexus AG ("Innoplexus") and Beckley Psytech Limited (collectively "non-consolidated VIEs") and determined that the investments are not VIEs as of the date of the Company's initial investment through December 31, 2024. The Company is not the primary beneficiary of the non-consolidated VIEs as it did not have the power to direct the activities that most significantly impact the investments' economic performance and therefore concluded that it did not have a controlling financial interest in each of the non-consolidated VIEs that would require consolidation as of December 31, 2024 and 2023.

The Company will reevaluate if the investments meet the definition of a VIE upon the occurrence of specific reconsideration events. The Company accounted for these investments under either the equity method, fair value option, or the measurement alternative included within ASC 321 (See Note 5). As of December 31, 2024, the Company's maximum exposure for its non-consolidated VIEs was $10.0 million of Short-term restricted cash for the purchase of Beckley Deferred Shares (as defined and described in Note 5).

As of December 31, 2023, the Company's maximum exposure for its non-consolidated VIE regarding IntelGenx was $6.1 million relating to the carrying values in its Other investments, $0.1 million of Long-term notes receivable – related party, net and $11.2 million of Convertible notes receivable - related party, each as shown in the consolidated balance sheets.

5. Investments

Other investments held at fair value

As of December 31, 2024 and 2023, the carrying values of Other investments held at fair value were as follows (in thousands):

	December 31, 2024	December 31, 2023
COMPASS Pathways plc	$ 26,104	$ 83,701
Beckley Psytech Additional Warrants	2,783	—
IntelGenx Technologies Corp.:		
2023 Subscription Agreement, as Amended	—	6,124
Total	$ 28,887	$ 89,825

COMPASS Pathways plc

COMPASS Pathways plc (“COMPASS”) is a mental health care company dedicated to pioneering the development of a new model of psilocybin therapy with its product COMP360. The Company first acquired investments in COMPASS in December 2018 with additional investments through 2021, and accounted for its investment under the equity method until August 2023. In August 2023, COMPASS closed its most recent financing round, in which the Company did not participate, and the Company's ownership interest in COMPASS was reduced to 15.4%.

Following the August 2023 financing, the Company evaluated its ability to continue to exercise significant influence over its investment and determined that it no longer had significant influence and as such will account for its COMPASS investment under ASC 321 at fair value. Any changes in fair value of the Company's investment in COMPASS will be recorded as a Change in fair value of assets and liabilities, net in its audited consolidated statements of operations.

In September 2024, the Company sold 2,660,000 American Depositary shares ("ADS") of COMPASS at a price of $6.05 per ADS in an open market transaction, resulting in net proceeds received of $16.1 million. The Company recognized a non-cash loss of $2.1 million on the sale during the year ended December 31, 2024, which is recorded as a component of Other income (expense), net in its consolidated statements of operations.

Based on quoted market prices, for the years ended December 31, 2024 and 2023, the fair value of the Company’s COMPASS investment was $26.1 million and $83.7 million, respectively. For the years ended December 31, 2024 and 2023, the Company recorded $39.4 million loss and $81.9 million gain related to changes in the fair value of the Company’s investment in Compass within Change in fair value of assets and liabilities, net in its consolidated statements of operations, respectively.

IntelGenx Technologies Corp.

In October 2024, the Company acquired all issued and outstanding shares of IGX (see Note 3). As of December 31, 2024, the Company continues to hold the following equity instruments of IntelGenx, which were all determined to have a carrying value of zero as IntelGenx continues to be party to proceedings under the CCAA.

2021 Securities Purchase Agreement

In May 2021, IntelGenx and the Company executed a Securities Purchase Agreement (the “IntelGenx SPA”) after obtaining IntelGenx shareholder approval, whereby IntelGenx issued shares of its common stock (the "IntelGenx Common Shares") and warrants to the Company at a price of approximately $12.3 million. The carrying amount of the investment was reduced to zero as of December 31, 2021. During the years ended December 31, 2024 and 2023, the Company did not recognize a change in fair value related to its investment in IntelGenx in the consolidated statements of operations. The carrying value of the investment remained at zero as of December 31, 2024 and 2023.

2023 Subscription Agreement, as Amended

In August 2023, IntelGenx and the Company entered into a subscription agreement (the “Subscription Agreement”), under which the Company paid IntelGenx $2.2 million for 2,220 convertible debenture units (the "2023 Initial Units"), with each convertible debenture unit consisting of:

i. $1,000 principal amount convertible promissory notes (the “2023 Initial Notes”) bearing interest at a rate of 12.0% per annum, payable quarterly in arrears beginning September 30, 2023, with all principal and accrued interest convertible into common shares of IntelGenx, at any time from the date that is six months following their issuance up to and including August 31, 2026 at a conversion price equal to $0.185 per common share; and

ii. 5,405 common share purchase warrants of IntelGenx (the “2023 Initial Warrants”), each exercisable at an exercise price of $0.26 per common share for a period of three years following their issuance.

Pursuant to the Subscription Agreement, the Company agreed to subscribe for an additional 750 convertible debenture units (the "2023 Subsequent Units") at a price of $750,000 subject to obtaining certain shareholder approvals. The Subsequent Units contain the same terms as the Initial Units, with each Subsequent Unit consisting of (i) $1,000 principal amount convertible promissory notes ("2023 Subsequent Notes") and (ii) 5,405 common share purchase warrants of IntelGenx ("2023 Subsequent Warrants").

Effective September 30, 2023, IntelGenx and the Company amended the Subscription Agreement (the “Amended Subscription Agreement”), allowing the Company, subject to obtaining certain shareholder approvals, the "Call Option" to purchase up to an additional

7,401 convertible debenture units (the “Call Option Units”). The Call Option Units contain the same terms as the Initial Units, with each Call Option Unit consisting of (i) $1,000 principal amount convertible promissory notes, and (ii) 5,405 common share purchase warrants of IntelGenx.

The issuance of any Call Option Unit shall result in a corresponding reduction in the Company's remaining purchase right pursuant to the IntelGenx SPA executed in May 2021 (the “2021 Purchase Right”), with such right to be reduced by the maximum number of shares of common stock issuable in connection with such Call Option Units, and (ii) in the event that the 2021 Purchase Right has been fully or partially exercised such that the aggregate number of shares of common stock issued thereunder together with the number of shares of common stock issuable in accordance with the Call Option Units would exceed 100,000,000, the number of shares of common stock that may be issued in connection with the Call Option Units shall be reduced such that the aggregate number of shares of common stock issued thereunder together with the number of shares of common stock issuable in accordance with the Call Option Units does not exceed 100,000,000. The maximum number of shares of common stock available under the 2021 Purchase Right was reduced from 130,000,000 shares of common stock to 100,000,000 shares of common stock, such that in no event shall the aggregate number of shares of common stock issuable in accordance with the Call Option Units and the 2021 Purchase Right exceed 100,000,000.

There are limits over the conversion of the Initial Units, Subsequent Units, Call Options Units and the IntelGenx Term Loan (as defined below in Note 6) into common shares.

The Company qualified for and elected to account for its investment in the convertible debenture units and call option under the fair value option. The Company believes that the fair value option better reflects the underlying economics of the convertible debenture units and call option. The convertible promissory notes are accounted for at fair value under ASC 320 and recorded in Short-term convertible notes receivable - related party in the consolidated balance sheets, as described further in Note 6. The warrants and call option are accounted for pursuant to the fair value option election and recorded in Other investments held at fair value in the consolidated balance sheets.

For the Initial Units, the Company applied a calibrated model and determined that the initial aggregate fair value of its $2.2 million investment was equal to the transaction price and recorded the 2023 Initial Notes at $1.5 million and the 2023 Initial Warrants at $0.7 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations. The Company will recognize subsequent changes in fair value of the Initial Units as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. As of December 31, 2024 and 2023, the fair value of the 2023 Initial Warrants was zero and $0.7 million, respectively. For the years ended December 31, 2024 and 2023, the Company recognized a $0.7 million loss and an immaterial change in Change in fair value of assets and liabilities, net relating to the 2023 Initial Warrants in its consolidated statements of operations, respectively.

In November 2023, upon shareholder approval, the Company paid $750,000 for the 2023 Subsequent Units. The Company applied a calibrated model and determined that the initial aggregate fair value of its $0.8 million investment was equal to the transaction price and recorded the 2023 Subsequent Notes at $0.6 million and the 2023 Subsequent Warrants at $0.2 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations. The Company will recognize subsequent changes in fair value of the Subsequent Units as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. As of December 31, 2024 and 2023, the fair value of the 2023 Subsequent Warrants was zero and $0.2 million, respectively. For the years ended December 31, 2024 and 2023, the Company recognized a $0.2 million loss and an immaterial change in Change in fair value of assets and liabilities, net relating to the 2023 Subsequent Warrants in its consolidated statements of operations, respectively.

In November 2023, upon shareholder approval, the Call Option had an estimated fair value of $5.1 million and is recorded in Other investments held at fair value in the consolidated balance sheets. As of December 31, 2024 and 2023, the fair value of the Call Option was zero and $5.2 million, respectively. For the years ended December 31, 2024 and 2023, the Company recognized a $5.2 million loss and a $0.1 million gain in Change in fair value of assets and liabilities, net relating to the Call Option in its consolidated statements of operations, respectively.

The Call Option is additional value conveyed to the Company relating to its investment in and Strategic Development Agreement with IntelGenx. Accordingly, the Company recognized a $5.1 million deferred credit, included in Other liabilities in the consolidated balance sheets as of December 31, 2023. The Company accounted for the deferred credit as a reduction of research and development expense in its consolidated statements of operations until the credit is exhausted or until the Company is no longer receiving goods or services from IntelGenx. Pursuant to the acquisition of IGX as described in Note 3, the Company has determined that it is no longer a customer of IntelGenx, as IGX has become a wholly-owned subsidiary as of October 2024. As such, the Company released the $5.1 million deferred

credit and recognized a $5.1 million gain, which is included in Gain on settlement of pre-existing contract in the consolidated statements of operations.

2024 Term Loan Warrants

In March 2024, the Company and IntelGenx entered into a third amendment to the amended and restated loan agreement (the "Third Amendment"), as further described in Note 6 below. In connection with the Third Amendment, the Company received warrants to purchase up to 4.0 million shares of IntelGenx Common Shares at an exercise price of $0.17, subject to certain adjustments and beneficial ownership limitations ("2024 Warrants"). The Company recorded the 2024 Warrants fair value of $0.4 million in Other investments held at fair value in the consolidated balance sheets, with a corresponding deferred vendor credit included in Other liabilities in the consolidated balance sheets. As of December 31, 2024, the 2024 Warrants have a fair value of zero. For the year ended December 31, 2024, the Company recorded a $0.4 million loss in Change in fair value of assets and liabilities, net for the change in fair value of the 2024 Warrants. Pursuant to the acquisition of IGX as described in Note 3, the Company has determined that it is no longer a customer of IntelGenx, as IGX has become a wholly-owned subsidiary as of October 2024. As such, the Company released the $0.4 million deferred credit and recognized a $0.4 million gain, which is included in Gain on settlement of pre-existing contract in the consolidated statements of operations.

Strategic Development Agreement

Prior to the Company's acquisition of IGX in October 2024 and pursuant to the Strategic Development Agreement, the Company engaged IntelGenx to conduct research and development projects (“Development Project”) using IntelGenx’s proprietary oral thin film technology. Under the terms of the Strategic Development Agreement, the Company could select four (4) program products. As of the effective date of the Strategic Development Agreement, the Company nominated two (2) program products - DMT and Salvinorin A. 20% of any funds that IntelGenx received or will receive through the Company’s equity investment under the IntelGenx SPA will be available to be credited towards research and development services that IntelGenx conducts for the Company under the Development Projects. The Company is eligible to receive a total credit of $2.5 million. For the years ended December 31, 2024 and 2023, research and development expense relating to the Strategic Development Agreement were $0.6 million and $0.7 million, respectively, which was applied as a reduction in research and development expenses in accordance with the Strategic Development Agreement.

Other investments

The Company’s investments in the preferred stock of Beckley Psytech Limited, GABA, defined below, and Innoplexus are not considered as in-substance common stock due to the existence of substantial liquidation preferences and therefore did not have subordination characteristics that were substantially similar to the common stock.

During the years ended December 31, 2024 and 2023, the Company evaluated all of its other investments to determine if certain events or changes in circumstance had a significant adverse effect on the fair value of any of its investments in non-consolidated entities. Based on this analysis, the Company did not note any impairment indicators associated with the Company’s Other investments.

During the years ended December 31, 2024 and 2023 there were no observable changes in price recorded related to the Company’s Other Investments.

As of December 31, 2024 and 2023, the carrying values of Other investments, which consisted of investments in the investee’s preferred stock and common stock not in the scope of ASC 323, were as follows (in thousands):

	December 31, 2024	December 31, 2023
Beckley Psytech Limited	$ 42,079	$ —
GABA Therapeutics, Inc.	—	1,838
Innoplexus AG	—	—
Total	$ 42,079	$ 1,838

Beckley Psytech Limited

Beckley Psytech Limited ("Beckley Psytech") is a clinical stage biotechnology company dedicated to improving the lives of people suffering from neuropsychiatric disorders by transforming psychedelics into effective and rapid-acting clinical medicines. Its most advanced programs are focused on the development of psychedelic-based medicines to treat people with treatment resistant depression and major depressive disorder.

Subscription and shareholders' agreement

On January 3, 2024, the Company entered into a subscription and shareholders' agreement with Beckley Psytech and certain other shareholders as identified in the agreement (the "SSA"). Pursuant to the terms of the SSA, the Company (a) has the right to acquire 24,096,385 newly issued series C preferred shares, par value £0.0001 per share, of Beckley Psytech (the “Series C Shares”) for a total purchase price of $40.0 million (the “Primary Investment”); and (b) undertakes to enter into a Share Purchase Deed (the “Secondary Sale SPA”) within 10 business days, pursuant to which the Company will acquire a total of 11,153,246 shares of Beckley Psytech from certain

existing shareholders of Beckley Psytech (the “Secondary Sale” and together with the Primary Investment, the “Investment”), all of which will be re-designated into Series C Shares immediately prior to completion of the Secondary Sale, for a total purchase price of $10.0 million. The Primary Investment is comprised of $25.0 million to be paid upon the closing of the SSA and an additional $15.0 million to be deposited under an Escrow Agreement (as defined below).

In connection with the SSA, the Company acquired, pursuant to an equity warrant instrument between the Company and Beckley Psytech, 24,096,385 warrants to purchase an amount of Series C shares equal to the lesser of (i) 24,096,385 Series C Shares; or (ii) such number of Series C Shares (rounded up to the nearest whole number) as immediately after their issuance would, together with all shares held by the Company in the issued share capital of Beckley Psytech, equal less than 50% of Beckley Psytech’s fully diluted share capital, and each such warrant is exercisable at an exercise price of $2.158 per share ("Series C Warrants").

Also under the SSA, the Company will have the right to receive additional warrants to purchase Series C Shares in the event Beckley Psytech issues equity or equity linked securities pursuant to a deferred equity arrangement in connection with a prior acquisition made by Beckley Psytech, each such warrant is exercisable at an exercise price of $1.66 per share. Each of the warrants described above is exercisable upon delivery of a written notice to Beckley Psytech ("Additional Warrants").

Initial Subscription

On January 3, 2024, the Company made the initial payment of $25 million for 15,060,241 Series C Shares at a subscription share price of $1.66 (“Initial Shares”) and delivered the executed deferred payment escrow agreement ("Escrow Agreement") to Beckley Psytech which was a condition for the closing or completion of the transaction (“Initial Subscription”).

Deferred Shares

On January 5, 2024, subject to the terms of the Escrow Agreement, the Company deposited $15.0 million into an escrow account. Prior to April 1, 2025, Beckley Psytech may, at its sole discretion, draw down up to $5.0 million from the escrow account, with the remaining balance to be paid to Beckley Psytech on April 1, 2025. Beckley shall credit as fully-paid such corresponding number of Series C Shares as corresponds with the value of each draw-down. The total number of deferred payment shares ("Deferred Shares") is 9,036,144 with a share price of $1.66.

Secondary Sale

On January 18, 2024, the Company and Beckley Psytech entered into the Secondary Sale SPA pursuant to which the Company agreed to purchase 11,153,246, £0.0001 par value, re-designated Series C shares (the “Secondary Sale Shares”) at a price of $0.8966 from the existing shareholders for an aggregate consideration of $10.0 million. On January 18, 2024, the Secondary Sale Shares were acquired by the Company.

Upon closing of the Initial Subscription, executed Escrow Agreement, and Secondary Sale Shares, the Company recognized a fair value of $35.3 million in Other Investments in the consolidated balance sheets related to the Initial Shares, Secondary Shares, and Series C Warrants and a fair value of $2.6 million in Other investments held at fair value related to the Additional Warrants.

The Company qualified for and elected to account for the investment acquired per the SSA using the measurement alternative under ASC 321, and is included in Other Investments in the consolidated balance sheets. The Company applied a calibrated model for the $35.3 million investment, to account for the Initial Shares, option to purchase the Deferred Shares, Secondary Shares, and Series C Warrants, on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations.

Pursuant to the Escrow Agreement, the Company recognized the fair value of the Deferred Shares as additional consideration for its investment in Beckley as the fair value of the Deferred Shares is less than the purchase price of $1.66 per share. The Company recognized a $2.9 million liability for the Deferred Shares recorded within Other current liabilities in its consolidated balance sheets. Upon Beckley drawing on the Escrow Agreement, the Company will reduce its liability related to the Deferred Shares and recognize gain or loss based on the fair value of the Series C shares as Other income (expense), net in the consolidated statements of operations.

Escrow Agreement Draw

In October 2024, pursuant to the terms of the Escrow Agreement, Beckley Psytech, at its sole discretion, drew $5.0 million from the escrow account and the Company was credited 3,012,048 Series C shares. The Company determined that the fair value of the shares received was $5.3 million, which is recorded as Other investments in the consolidated balance sheets. The Company recognized a gain of $1.3 million related to the investment for the year ended December 31, 2024, which is recognized as Other income (expense), net in the consolidated statements of operations. The Company reflects the remaining $10.0 million held in escrow in Short-term restricted cash for other investments within the consolidated balance sheets as of December 31, 2024. The Company reflects the remaining $1.9 million liability related to the Deferred Shares in Other current liabilities within the consolidated balance sheets as of December 31, 2024.

Additional Warrants

The Company determined that the Additional Warrants meet the definition of a derivative instrument under ASC 815 and recorded the $2.6 million fair value at the transaction date in Other investments held at fair value in the consolidated balance sheets, with subsequent changes in fair value being reflected through the consolidated statements of operations in the Change in fair value of assets and liabilities, net.

In May 2024, Beckley Psytech issued equity pursuant to the deferred equity arrangement, and, per the SSA, the Company received 4,393,400 warrants. The Company determined that once received the Additional Warrants will no longer meet the definition of a derivative instrument under ASC 815. The Company qualified for and elected to account for the warrants under ASC 321, and recorded the warrants received in Other Investments in the consolidated balance sheets. At the time of receipt, the warrants had a fair value of $1.5 million.

As of December 31, 2024, the remaining Additional Warrants had a fair value of $2.8 million recorded in Other investments held at fair value in the consolidated balance sheets. For the year ended December 31, 2024, the Company recorded a $1.7 million gain in the Change in fair value of assets and liabilities, net in its consolidated statements of operations.

GABA Therapeutics, Inc.

GABA is a California based biotechnology company focused on developing GRX-917 for anxiety, depression and a broad range of neurological disorders. The Company is deemed to have significant influence over GABA through its total ownership interest in GABA's equity, including the Company's investment in GABA's preferred stock, and the Company's noncontrolling representation on GABA's board of directors.

Common Stock Investment

The Company's investment in GABA's common stock was accounted for in accordance with the equity method.

In November 2020 the Company exercised its option to purchase additional shares of common stock of GABA at a price of approximately $1.8 million pursuant to an Omnibus Amendment Agreement under which the Right of First Refusal and Co-Sale Agreement was amended. Pursuant to the amended Right of First Refusal and Co-Sale Agreement, the Company also has the option but not the obligation to purchase additional shares of common stock for up to $2.0 million from the existing common shareholders.

The carrying value of the investment in GABA common stock was reduced to zero as of December 31, 2020 due to IPR&D charges with no alternative future use and remained zero as of December 31, 2024.

Preferred Stock Investment

The Company's investment in GABA's preferred stock did not meet the criteria for in-substance common stock. As such, the investment in GABA's preferred stock is accounted for under the measurement alternative.

In August 2019, GABA and the Company entered into the Preferred Stock Purchase Agreement (the "GABA PSPA"), whereby GABA issued shares of its Series A preferred stock to the Company at a price of approximately $5.5 million. At closing, the Company had an overall ownership interest of over 20% in GABA and a noncontrolling representation on the board.

Pursuant to the GABA PSPA, the Company was obligated to purchase additional shares of Series A preferred stock for up to $10.0 million with the same price per share as its initial investment, upon the achievement of specified contingent clinical development milestones. In April 2021, pursuant to the GABA PSPA, the Company purchased additional shares of Series A preferred stock of GABA, for an aggregate cost of $5.0 million based on the achievement of certain development milestones. In May 2021, the Company exercised its option to purchase additional shares of Series A preferred stock prior to the achievement of certain development milestone for an aggregate cost of $5.0 million completing its obligation to purchase additional shares. The completion of the Series A Preferred stock purchase in May 2021 was deemed to be a reconsideration event at which point GABA was no longer deemed a VIE as GABA now had sufficient equity at risk to finance its activities through the initial development period without additional subordinated financial support. Entities that do not qualify as a VIE are assessed for consolidation under the voting interest model ("VOE model"). Under the VOE model, the Company consolidates the entity if it determines that it, directly or indirectly, has greater than 50% of the voting shares and that other equity holders do not have substantive voting, participating or liquidation rights. While the Company holds greater than 50% of the outstanding equity interest of GABA, the Company does not have the power to control the entity. Concurrent with the exercise of the option, the Company executed a side letter with the other equity holders of GABA agreeing to forego the rights to additional seats on the board of directors, resulting in the Company lacking the ability to control the investee. The Company concluded that it does not have a controlling financial interest that would require consolidation under the VOE model and accounted for the investments in GABA preferred stock under the measurement alternative per ASC 321.

In May 2021, GABA and the Company entered into an Amendment to Preferred Stock Purchase Agreement (the "Amended GABA PSPA") under which the GABA PSPA was amended and shares of its Series A preferred stock were issued to the Company at a price of approximately $0.6 million. Pursuant to the Amended GABA PSPA, the Company is obligated to purchase additional shares of Series A preferred stock from GABA for up to $1.5 million with the same price per share as its initial investment upon the achievement of specified contingent clinical development milestones. In September 2022, pursuant to the Amended PSPA, GABA issued additional shares of its

Series A preferred stock to the Company at a price of approximately $0.6 million based on the achievement of certain development milestones. As of December 31, 2024, the Company's remaining obligation to purchase additional shares of Series A preferred stock from GABA is for up to $0.9 million at the same price per share as its initial investment upon the achievement of specified contingent milestones.

In accordance with the Amended GABA PSPA, the Company also has the option to purchase the aforementioned additional shares of Series A preferred stock at any time prior to the achievement of any milestone at the same price per share as its initial investment.

GABA's net losses attributable to the Company were determined based on the Company's ownership percentage of preferred stock in GABA and recorded to the Company's investments in GABA preferred stock. As of December 31, 2024 and 2023, the investment in GABA's preferred stock is zero and $1.8 million, and is recorded in Other investments in the consolidated balance sheets. During the year ended December 31, 2024 and 2023, the Company recognized its proportionate share of GABA's net loss of $2.0 million and $3.6 million, respectively, as Losses from investments in equity method investees, net of tax on the consolidated statements of operations.

Innoplexus AG

Innoplexus AG is a technology company that provides "Data as a Service" and "Continuous Analytics as a Service" solutions that aims to help healthcare organizations leverage their technologies and expedite the drug development process across all stages—preclinical, clinical, regulatory and commercial. The Company first acquired investments in Innoplexus in August 2018, which consisted of common stock and preferred stock.

As of December 31, 2020, the Company owned 35.0% of the common stock issued by Innoplexus. The Company has significant influence over Innoplexus through its noncontrolling representation on the investee's supervisory board. Accordingly, the Company's investment in Innoplexus' common stock was accounted for in accordance with the equity method. The Company's investment in Innoplexus' preferred stock did not meet the criteria for in-substance common stock. As such, the investment in Innoplexus' preferred stock was accounted for under the measurement alternative as discussed below.

In February 2021, the Company entered into a Share Purchase and Assignment Agreement (the "Innoplexus SPA") to sell its shares of common and preferred stock held in Innoplexus to a current investor of Innoplexus (the "Purchaser") in exchange for an initial purchase price of approximately $2.4 million. In addition, the Company is entitled to receive contingent payments based on the occurrence of subsequent equity transactions or liquidity events at Innoplexus as determined under the Innoplexus SPA.

Pursuant to the Innoplexus SPA, the Purchaser is required to hold a minimum number of shares equivalent to the number of shares purchased from the Company through December 31, 2026. In the event that the Purchaser is in breach of this requirement, the purchaser is required to pay the Company an additional purchase price of approximately $9.6 million. The transaction was accounted for as a secured financing as it did not qualify for sale accounting under ASC Topic 860, *Transfers and Servicing* (ASC 860), due to the provision under the Innoplexus SPA which constrained the Purchaser from its right to pledge or exchange the underlying shares and provided more than a trivial benefit to the Company. The initial proceeds from the transaction are reflected as a secured borrowing liability of $2.2 million as of December 31, 2024 and 2023, which is included in Other liabilities in the Company's consolidated balance sheets. The Company will continue to account for its investment in Innoplexus' common stock under the equity method of accounting and its investment in Innoplexus' preferred shares under the measurement alternative.

In addition, the Innoplexus SPA also provides the rights for the Company to receive additional consideration with a maximum payment outcome of $22.3 million should the equity value of Innoplexus exceed certain thresholds upon the occurrence of certain events. The Company concluded that this feature met the definition of a derivative which required bifurcation. As the probability of the occurrence of certain events defined in the Innoplexus SPA was less than remote, the Company concluded that the fair value of the embedded derivative ascribed to this feature was de minimis for the years ended December 31, 2024 and 2023.

The carrying value of the Company's investment in Innoplexus was zero as of December 31, 2024 and December 31, 2023.

The Company's ownership of Innoplexus common stock was 35.0% as of December 31, 2024 and December 31, 2023.

DemeRx NB, Inc.

In December 2019, the Company jointly formed DemeRx NB, Inc. ("DemeRx NB") with DemeRx Inc. DemeRx Inc. and DemeRx NB entered into a Contribution Agreement whereby DemeRx inc. assigned all of its rights, title, and interests in and to all of its assets relating to DMX-1002, Noribogaine, in exchange for shares of common stock of DemeRx NB. DemeRx NB will use the contributed intellectual property to develop Noribogaine. Noribogaine is an active metabolite of ibogaine designed to have a longer plasma half-life and potentially reduced hallucinogenic effects compared to ibogaine.

In connection with the Contribution Agreement, the parties entered into a Series A Preferred Stock Purchase Agreement (the "DemeRx NB PSPA") pursuant to which the Company purchased shares of Series A preferred stock of DemeRx NB at a purchase price of $1.0 million. At closing, the Company had less than 20% of ownership interest in DemeRx NB and a noncontrolling representation on DemeRx NB's board of directors. The investment in DemeRx NB was recorded in Other investments on the consolidated balance sheets under the measurement alternative under ASC 321.

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.'s equity ownership of DemeRx IB (the "Stock Purchase"), in exchange for consideration that included, among other items, the transfer of the Company's ownership in DemeRx, NB, Inc. to DemeRx, Inc. In connection with the Stock Purchase, the Company assessed the fair market value of its DemeRx NB investment and determined that it had been impaired. As a result, the Company recognized a $1.0 million impairment loss in Impairment of other investments, a component of other income, net in the consolidated statements of operations for the year ended December 31, 2023.

Juvenescence Limited

During the year ended December 31, 2023, the Company divested its investment in Juvenescence Limited ("Juvenescence") and recognized a $0.1 million gain on the transaction reflected in Other income (expense), net on the consolidated statements of operations. Prior to the divestment of Juvenescence, the Company's investment was in common stock, however, it was not able to exercise significant influence over the operating and financial decisions of Juvenescence.

Summarized Financial Information

The following is a summary of financial data for investments accounted for under the equity method of accounting (in thousands):

Balance Sheets

	December 31, 2024	December 31, 2023
	GABA	GABA
Current assets	$ 112	$ 1,720
Total assets	$ 112	$ 1,720
Current liabilities	$ 2,805	$ 1,546
Total liabilities	$ 2,805	$ 1,546

Statements of Operations

	For the year ended December 31, 2024	For the year ended December 31, 2023	Nine Months Ended September 30, 2023
	GABA	GABA	COMPASS [(i)]
Loss from continuing operations	$ (3,227)	$ (3,593)	$ (98,514)
Net loss	$ (3,227)	$ (3,593)	$ (85,932)

[(i)] As of August 18, 2023, the Company determined that it no longer had significant influence. At this remeasurement date, the Company qualified for and elected to account for its investment in COMPASS under the fair value option. Summarized financial information is as of and for the nine month period ending September 30, 2023 as this information is not readily available as of August 18, 2023 and the Company has no practical way to estimate otherwise.

6. Notes Receivable

IntelGenx Technologies Corp.

Prior to the Company's acquisition of IGX in October 2024, the Company had outstanding loan agreements and convertible notes with IntelGenx, as described below. The Company discharged its secured debt it held with IntelGenx in consideration for IGX, which included the DIP Loan and the IntelGenx Term Loan. The Company continues to hold the 2023 Initial Notes, the 2023 Subsequent notes, and the IntelGenx 2023 Term Loan Note with IntelGenx, which continues to be subject to protections under the CCAA. The Company determined that the fair value of the 2023 Initial Notes, the 2023 Subsequent notes, and the IntelGenx 2023 Term Loan Note with IntelGenx is zero as of December 31, 2024.

IntelGenx Term Loan, as amended

In March 2021, the Company and IntelGenx entered into a loan agreement (the "Original Loan Agreement") under which the Company provided a loan to IntelGenx for an aggregate principal amount of $2.0 million. In May 2021, the Company paid an additional advance of $0.5 million as an additional term loan. In September 2021, the Company entered into an amended and restated loan agreement which, among other things, increased the principal amount of loans available to IntelGenx by $6.0 million, for a total of up to $8.5 million. The additional $6.0 million loan amount was funded via two separate $3.0 million tranches. The first $3.0 million tranche was funded in January 2022 and the second $3.0 million tranche was funded in January 2023. The loan bears an annualized interest rate of 8% and such interest is accrued daily. The Company recorded this loan at cost in Long-term notes receivable - related parties, net on the consolidated balance sheets.

On January 1, 2023, the Company adopted ASU 2016-13, Financial Instruments - Credit Losses, as further discussed in Note 2, which resulted in a $0.4 million increase to accumulated deficit and allowance for credit losses related to the IntelGenx loan.

In August 2023, the Company and IntelGenx entered into the first amendment to the amended and restated loan agreement (the "First Amendment") which, among other things, extended the maturity date from January 5, 2024 to January 5, 2025 and granted the Company additional security over any non-licensed intellectual property owned or controlled by IntelGenx. The Company determined that this modification did not have a material impact on the amortized cost basis of the IntelGenx Term Loan (as defined below).

Effective September 30, 2023, the Company and IntelGenx entered into a second amendment to the amended and restated loan agreement (the "Second Amendment", and together with the Original Loan Agreement and the First Amendment, the "IntelGenx Term Loan") which, subject to obtaining certain shareholder approvals, entitles the Company to convert any portion of the outstanding and unpaid principal and accrued interest into common shares of IntelGenx at a conversion price per share of $0.185 (the "Conversion Feature"). There are limits over the conversion of the IntelGenx Term Loan, along with Initial Units, Subsequent Units, and Call Options Units into common shares.

In November 2023, upon shareholder approval, the Conversion Feature was effective. The Company evaluated this modification subject to accounting guidance in ASU 2022-02, Financial Instruments - Credit Losses and determined the Conversion Feature is considered the addition of a substantive conversion option and the modification is more than minor. Therefore, the Second Amendment should be treated as an extinguishment of the existing loan and the issuance of a new convertible debt instrument. The IntelGenx Term Loan, as amended, meets the definition of a security and will be accounted for under ASC 320. Pursuant to the remeasurement event, the Company is eligible and has elected the fair value option to account for its investment in the IntelGenx Term Loan. The Company believes that the fair value option better reflects the underlying economics of the loan. The Company recorded the new convertible debt instrument at its fair value of $9.2 million in Convertible notes receivable - related party on the consolidated balance sheets. The existing carrying value of the extinguished loan was $9.3 million ($8.5 million of principal and $1.2 million of accrued interest, net of $0.4 million allowance for credit losses). The difference of $0.1 million was recorded as an extinguishment loss and included in Change in fair value of assets and liabilities, net in the consolidated statements of operations. The IntelGenx Term Loan was subsequently remeasured at each reporting date until settled or converted. The Company recognized subsequent changes in fair value of the IntelGenx Term Loan in Change in fair value of assets and liabilities, net, a component of other income (expense), net in its consolidated statements of operations.

In March 2024, the Company and IntelGenx entered into the Third Amendment (together with the Original Loan Agreement, the First Amendment, and the Second Amendment, the “IntelGenx Term Loan”) pursuant to which the Company immediately provided an additional $1.0 million term loan (“Tranche 1 Additional Term Loan”), and would provide an additional $1.0 million term loan (“Tranche 2 Additional Term Loan”) contingent upon certain of the Company's clinical milestones. The IntelGenx Term Loan, as amended includes a conversion feature that allows for:

i. any portion of the outstanding and unpaid principal under the Initial Tranches and/or the Tranche 1 Additional Term Loan into conversion shares (the “Conversion Shares”) at a conversion price per share of $0.185 (the “Initial Conversion Price”);

ii. any accrued interest under the Initial Tranches into Conversion Shares at the Initial Conversion Price;

iii. any portion of the outstanding and unpaid principal under the Tranche 2 Additional Term Loan into Conversion Shares at a conversion price per share equal to the greater of: (1) the Initial Conversion Price; and (2) the 5-day volume-weighted average

price (the “5-day VWAP”) of the Shares, less the maximum permitted discount under the applicable rules of the Stock Exchange, ending on the date immediately prior to the advancement of the Tranche 2 Additional Term Loan (the “Tranche 2 Conversion Price”); and

iv. any accrued interest under the Tranche 1 Additional Term Loan into Conversion Shares at the 5-day VWAP of the shares, less the maximum permitted discount under the applicable rules of the Stock Exchange, ending on the day that is the second business day before the day the Interest become due and payable (the “Interest Conversion Price” and, together with the Initial Conversion Price and the Tranche 2 Conversion Price, the “Conversion Price”), subject to Stock Exchange approval.

In connection with the Third Amendment, the Company received warrants to purchase up to 4.0 million shares of IntelGenx Common Shares at an exercise price of $0.17, subject to certain adjustments and beneficial ownership limitations, which were recorded at fair value of $0.4 million in Other investments held at fair value in the consolidated balance sheets, with a corresponding deferred vendor credit included in Other liabilities in the consolidated balance sheets. See Note 5 above for further discussion.

As a result of the Third Amendment, the Company recorded the Tranche 1 Additional Term Loan principal of $1.0 million in Convertible notes receivable – related party on the consolidated balance sheets.

In May 2024, the Company paid the Tranche 2 Additional Term Loan and recorded the principal of $1.0 million in Convertible notes receivable – related party on the consolidated balance sheets.

Immediately prior to the Company's acquisition of IGX in October 2024, the Company estimated that the fair value of the underlying collateral of the secured debt was less than the principal and interest of the DIP Loan (as defined below). As the DIP Loan is senior secured, the Company determined that the fair value of the IntelGenx Term Loan was zero and IntelGenx Term Loan was subsequently discharged on the acquisition date. As of December 31, 2023, the $8.6 million fair value of the amended IntelGenx Term Loan was recorded in Convertible notes receivable – related party on the consolidated balance sheets. For the years ended December 31, 2024 and 2023, the Company recognized a loss of $10.9 million and $0.3 million, respectively, in Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations for the reduction in fair value of IntelGenx Term Loan.

For the years ended December 31, 2024 and 2023, the Company recognized zero and $0.6 million of interest income, respectively, associated with the IntelGenx Term Loan.

IntelGenx Convertible Notes

On August 30, 2023, the Company and IntelGenx entered into the Subscription Agreement (as further described in Note 5), under which the Company paid IntelGenx $2.2 million for 2,220 convertible debenture units (the "Initial Units"), with each convertible debenture unit consisting of (i) $1,000 principal amount convertible promissory notes (the “2023 Initial Notes”); and (ii) 5,405 common share purchase warrants of IntelGenx.

The 2023 Initial Notes are accounted for at fair value under ASC 320 and recorded in Convertible notes receivable - related party in the consolidated balance sheets. The Company applied a calibrated model and determined that the initial aggregate fair value of its $2.2 million investment was equal to the transaction price and recorded the 2023 Initial Notes at $1.5 million and the 2023 Initial Warrants at $0.7 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations. The Company will recognize unpaid interest and subsequent changes in fair value of the 2023 Initial Notes as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

In November 2023, upon shareholder approval, the Company paid $750,000 for the 2023 Subsequent Units (as further described in Note 5), which included the 2023 Subsequent Notes. The 2023 Subsequent Notes are accounted for at fair value under ASC 320 and recorded in Convertible notes receivable - related party in the consolidated balance sheets. The Company applied a calibrated model and determined that the initial aggregate fair value of its $0.8 million investment was equal to the transaction price and recorded the 2023 Subsequent Notes at $0.6 million and the 2023 Subsequent Warrants at $0.2 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations. The Company will recognize unpaid interest and subsequent changes in fair value of the 2023 Subsequent Notes as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

The Company has estimated the fair value of various notes receivables with IntelGenx based on the fair value of the underlying collateral of the secured debt. As the 2023 Initial Notes and 2023 Subsequent Notes are not secured by underlying collateral, the Company has determined the fair value of the 2023 Initial Notes and 2023 Subsequent Notes are zero, respectively as of December 31, 2024. As of December 31, 2023, the fair value of the 2023 Initial Notes and 2023 Subsequent Notes was $1.8 million and $0.5 million, respectively, and recorded in Convertible notes receivable - related party in the consolidated balance sheets.

For the years ended December 31, 2024 and 2023, the Company recognized losses of $1.8 million and $0.3 million within Change in fair value of assets and liabilities, net relating to the 2023 Initial Notes, respectively, in its consolidated statements of operations. For the years

ended December 31, 2024 and 2023, the Company recognized losses of $0.5 million and an immaterial amount within Change in fair value of assets and liabilities, net relating to the 2023 Subsequent Notes, respectively, in its consolidated statements of operations.

IntelGenx 2023 Term Loan Note

In December 2023, the Company and IntelGenx entered into a new term loan agreement under which the Company provided the aggregate principal amount of $500,000 (the “2023 Term Loan Note”). The loan bears an annualized interest rate of 14.0% compounding monthly. Principal and interest outstanding shall be due and payable from proceeds of future IntelGenx fundraising. The outstanding principal and interest on the 2023 Term Loan Note is due and payable on the earlier of December 31, 2024 or the bankruptcy, receivership or insolvency of IntelGenx. The outstanding principal and interest on the 2023 Term Loan Note is due and payable under the terms of the agreement.

The Company qualified for and elected to account for the 2023 Term Loan Note under the fair value option. The Company believes that the fair value option better reflects the underlying economics of the 2023 Term Loan Note. The IntelGenx 2023 Term Loan Note is accounted for at fair value under ASC 825 and recorded in Short-term notes receivable - related party, net in the consolidated balance sheets. The Company will recognize unpaid interest and subsequent changes in fair value of the IntelGenx 2023 Term Loan Note as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

The Company has estimated the fair value of various notes receivables with IntelGenx based on the fair value of the underlying collateral of the secured debt. As the 2023 Term Loan Note is not secured by underlying collateral, the Company has determined the fair value of the 2023 Term Loan Note is zero as of December 31, 2024. As of December 31, 2023, the 2023 Term Loan Note had a fair value of $0.5 million and recorded in Short-term notes receivable - related party, net.

For the years ended December 31, 2024 and 2023, the Company recognized a $0.5 million loss and an immaterial loss, respectively, in Change in fair value of assets and liabilities, net relating to the IntelGenx 2023 Term Loan Note in its consolidated statements of operations.

Debtor-in-Possession Loan

In May 2024, pursuant to the Initial Order authorizing the DIP Financing, the Company and IntelGenx entered into a senior secured super-priority, interim, non-revolving multiple draw credit facility ("DIP Loan") up to a maximum of CDN $8.0 million. The DIP Loan bears an annualized interest rate equal to the National Bank of Canada prime rate. The outstanding principal and interest of the DIP Loan is due and payable on the earlier of (i) September 30, 2024, (ii) the termination of the stay period in the CCAA proceedings, (iii) the CCAA proceedings are converted into a bankruptcy or receivership, (iv) implementation of a restructuring plan or sale of the IntelGenx business during the CCAA proceedings, or (v) an event of default as defined in the DIP Loan agreement.

The Company qualified for and elected to account for the DIP Loan under the fair value option. The Company believed that the fair value option better reflects the underlying economics of the DIP Loan. The DIP Loan was accounted for at fair value under ASC 825 and recorded in Short term notes receivable - related party, net in the consolidated balance sheets. The Company recognized unpaid interest and subsequent changes in fair value of the DIP Loan Note as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. Prior to the Company's acquisition of IGX in October 2024, IntelGenx drew CDN $7.8 million (USD $5.7 million) pursuant to the DIP Loan.

Immediately prior to the Company's acquisition of IGX, the Company estimated the fair value of the DIP Loan to be based on the fair value of the underlying collateral of IntelGenx's secured debt and the relative seniority of the debt. The fair value of the DIP Loan immediately prior to the IGX acquisition was $5.7 million, and the DIP Loan was subsequently discharged as of the acquisition date. For the year ended December 31, 2024, the Company recognized an immaterial change in Change in fair value of assets and liabilities, net relating to the DIP Loan in its consolidated statements of operations.

Subsequent DIP Loan Commitment

Upon entering into the DIP Loan in May 2024, the Company was obligated to fund IntelGenx up to CDN $8.0 million. Accordingly, the Company recognized a liability and related expense of $0.7 million for the remaining committed and unpaid balance of the DIP Loan as of June 30, 2024 ("Subsequent DIP Loan Commitment"). The Subsequent DIP Loan Commitment was accounted for at fair value under ASC 825 and was recognized within Other current liabilities in the consolidated balance sheets, with the related expense recognized as Other income (expense), net in the consolidated statements of operations. As the Company made further payments pursuant to the DIP Loan, it recognized a reduction in the Subsequent DIP Loan Commitment liability and recognized a related gain within Other income (expense), net, in the consolidated statements of operations. Accordingly, the Company recognized a related gain of $0.5 million during the three months ended September 30, 2024 and an additional gain of $0.2 million during the three months ended December 31, 2024, all recorded within Other income (expense), net the consolidated statements of operations.

Immediately prior to the Company's acquisition of IGX, the fair value of the Subsequent DIP Loan Commitment was zero as the DIP Loan was discharged in consideration for the acquisition of IGX, resulting in no remaining future committed payments.

DemeRx Promissory Note

In January 2020, DemeRx IB loaned to DemeRx Inc. $1.0 million pursuant to the terms of a Promissory Note (the "DemeRx Note"). Pursuant to the terms of the DemeRx Note, the aggregate principal amount of $1.0 million together with all accrued and unpaid interest and any other amounts payable are due to be paid on the date that is the earlier of (i) 5 years from the initial closing and (ii) the closing of an initial public offering or a deemed liquidation event of DemeRx IB (the “DemeRx Maturity Date”). Pursuant to the terms of the DemeRx Note, DemeRx Inc. may, in its sole discretion pay any amount due under the DemeRx Note, in cash or through cancellation shares of common stock of DemeRx IB, par value $0.0001 per share, of the fair market value of such shares.

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.’s equity ownership of DemeRx IB (the “Stock Purchase”). The Stock Purchase, a liquidation event, required a repayment of the DemeRx Note. Pursuant to the terms of the DemeRx Note, DemeRx, Inc opted to repay the outstanding balance through the cancellation of its shares of common stock of DemeRx IB.

For the years ended December 31, 2024, and 2023, the Company did not earn any interest income associated with the DemeRx Note.

7. Fair Value Measurement

The following table presents information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation (in thousands):

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 6,196	$ —	$ —	$ 6,196
Investment in securities at fair value:				
U.S. treasuries	—	44,825	—	44,825
Other investments held at fair value	26,104	—	2,783	28,887
	$ 32,300	$ 44,825	$ 2,783	$ 79,908
Liabilities:				
Contingent consideration liability - related party	$ —	$ —	$ 110	$ 110
Contingent consideration liabilities	—	—	212	212
Convertible promissory note conversion option - related party	—	—	995	995
Convertible promissory note conversion option	—	—	1,616	1,616
	$ —	$ —	$ 2,934	$ 2,934

	Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 56	$ —	$ —	$ 56
Investment in securities at fair value:				
U.S. treasuries	—	67,119	—	67,119
Corporate notes/bonds	—	5,007	—	5,007
U.S. government agencies	—	37,097	—	37,097
Other investments held at fair value	83,701	—	6,124	89,825
Convertible notes receivable - related party	—	—	11,202	11,202
	$ 83,757	$ 109,223	$ 17,326	$ 210,306
Liabilities:				
Contingent consideration liability - related party	$ —	$ —	$ 620	$ 620
Contingent consideration liabilities	—	—	1,637	1,637
2018 convertible promissory note conversion option	—	—	2,385	2,385
	$ —	$ —	$ 4,643	$ 4,643

Investment in securities at fair value

The Company elected the fair value option for the securities in its investment portfolio. The fair value is based on quoted market prices, when available. When a quoted market price is not readily available, the Company uses the market price from its last sale of similar assets. The cash and cash equivalents held by the Company are categorized as Level 1 investments as quoted market prices are readily available for these investments. All other investments in the investment portfolio are categorized as Level 2 investments as inputs utilized to fair value these securities are either directly or indirectly observable, such as the market price from the last sale of similar assets.

The unrealized gains and losses on the available-for-sale securities, represented by change in the fair value of the investment portfolio, is reported in earnings. Since the investment in the available-for-sale securities are already measured at fair value, no separate credit losses would be recorded in the financials.

For the year-ended December 31, 2024 and 2023, the Company recognized a $3.8 million and $5.5 million gain related to the change in fair value in its available for sale securities recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations.

Other investments held at fair value

COMPASS Pathways plc

As described in Note 5 above, pursuant to the August 2023 financing, the Company determined that it no longer had significant influence and accounted for its COMPASS investment at fair value under ASC 321 with any changes in fair value recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations. The Company determines the fair value of its COMPASS investment by taking the publicly available share price as of the balance sheet date multiplied by the number of shares the Company holds. There are no non-observable inputs in determining the fair value. For the years ended December 31, 2024 and 2023, the Company recognized a $39.4 million loss and a $81.9 million gain within Change in fair value of assets and liabilities, net, respectively.

Beckley Psytech

As described in Note 5, the Company determined that the Additional Warrants meet the definition of a derivative instrument under ASC 815 and recorded the Additional Warrants at fair value with subsequent changes in fair value being reflected through the consolidated statements of operations in the Change in fair value of assets and liabilities, net. The Additional Warrants have a fair value of $2.8 million as of December 31, 2024.

The significant unobservable inputs that are included in the valuation of the Additional Warrants as of December 31, 2024 are (i) probability of issuances under the deferred equity arrangement of 55%-80%, and (ii) volatility of 95%.

IntelGenx Technologies Corp.

As described in Note 5, prior to the completion of the Company's acquisition of IGX in October 2024, the Company's investment in IntelGenx included common shares, 2023 Initial Warrants, 2023 Subsequent Warrants, and 2024 Warrants, (the 2023 Initial Warrants, 2023 Subsequent Warrants, and 2024 Warrants are collectively referred to as the “Warrants”), and Call Option. The Company determined that the Warrants and the Call Option did not meet the definition of a derivative instrument under ASC 815. The Company classified the common shares as Level 2 assets and the Warrants and the Call Option as Level 3 assets in the fair value hierarchy. The Warrants and Call Option were measured at fair value on a quarterly basis and any changes in the fair value were recorded as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

Considering the aforementioned facts and circumstances in Note 3 and Note 5, the Company estimated a zero fair value to be attributable to the Warrants and the Call Option as of December 31, 2024.

As of December 31, 2023, the Warrants and Call Option were recorded at fair value utilizing the Black-Scholes option pricing model. The Black Scholes option pricing model was based on the estimated market value of the underlying IntelGenx Common Shares at the valuation measurement date, the remaining contractual term of the Warrants and Call Option, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying IntelGenx Common Shares. The expected volatility was based on a peer group volatility which is a Level 3 input within the fair value hierarchy. As of December 31, 2023, the fair value of the 2023 Initial Warrants, the 2023 Subsequent Warrants and Call Option was $0.7 million, $0.2 million and $5.2 million, respectively, and was recorded in Other investments held at fair value in the consolidated balance sheets.

The significant unobservable inputs that were included in the valuation of the Initial Warrants, 2023 Initial Warrants, 2023 Subsequent Warrants and Call Option as of December 31, 2023 were (i) estimated market value of the underlying common stock of $0.13, including discount for lack of marketability and (ii) volatility of 100%.

An additional significant unobservable input that was included in the valuation of the Call Option as of December 31, 2023 was discount rate of 45.9% based on an assessment of IntelGenx credit risk and market yields of companies with similar credit risk.

IntelGenx notes receivable

As described in Note 6, prior to October 2024, the Company's notes receivable with IntelGenx included the IntelGenx Term Loan, the 2023 Initial Notes, the 2023 Subsequent Notes, the DIP Loan, and the 2023 Term Loan Note. The fair value of these instruments were estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

For the year ended December 31, 2023, the fair value of the 2023 Initial Notes and the 2023 Subsequent Notes were estimated using a Binomial Lattice in a risk-neutral framework (a special case of the Income Approach). Specifically, the future stock price of IntelGenx was modeled assuming a Geometric Brownian Motion in a risk-neutral framework. For each modeled future price, the 2023 Initial Notes and the 2023 Subsequent Notes were calculated based on the contractual terms (incorporating any optimal early exercise), and then discounted at the term-matched risk-free rate. Finally, the value of the 2023 Initial Notes and the 2023 Subsequent Notes were calculated as the probability-weighted present value over all future modeled payoffs. Additionally, the fair value of the 2023 Term Loan Note was estimated as the present value of the debt cash-flows plus the fair value of the Conversion Feature. The Conversion Feature fair value was estimated utilizing the Black-Scholes option pricing model. The Black Scholes option pricing model was based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the Conversion Feature, risk-free interest

rates, expected dividends, and expected volatility of the price of the underlying common stock. The expected volatility was based on a peer group volatility which is a Level 3 input within the fair value hierarchy.

As described in Note 3 above, the Company served as a Stalking Horse for IntelGenx as they sought protection from creditors under the CCAA. The Company's bid was to acquire certain assets and liabilities of IntelGenx in exchange for the discharge of all senior secured debt payable by IntelGenx, which included the DIP Loan and the IntelGenx Term Loan. The underlying collateral of such senior secured debt was determined to be the net assets and liabilities of IGX as acquired by the Company and as included in the Company's Stalking Horse proposal. Accordingly, the Company has estimated the fair value of the underlying collateral, which included the fair value of the acquired intangible assets, based on a probability adjusted forecasted revenue and expenses and a discount rate of 12.5%. The Company adjusted the fair value of the DIP Loan to agree to this determined fair value of the net assets and liabilities acquired. As of the Company's acquisition date of IGX in October 2024, the fair value of the DIP Loan was $5.7 million and the fair value of the IntelGenx Term Loan was zero.

Considering relevant facts and circumstances, the Company estimated the fair value attributable to the various notes receivables with IntelGenx based on the remaining fair value of the underlying collateral. As the 2023 Initial Notes, 2023 Subsequent Notes, and the 2023 Term Loan Note (collectively the "IntelGenx Unsecured Debt") were not secured by the underlying collateral, the Company determined the fair value of IntelGenx Unsecured Debt to be zero as of December 31, 2024.

IntelGenx Subsequent DIP Loan Commitment

As described in Note 6, there are no additional commitments under the DIP Loan as of the IGX acquisition date in October 2024. Accordingly, the fair value of the Subsequent DIP Loan Commitment was reduced to zero as of the acquisition date and remained zero as of December 31, 2024.

Contingent consideration liability - related party

The contingent consideration liability - related party in the table above relates to milestone and royalty payments in connection with the acquisition of Perception Neuroscience Holdings, Inc. (“Perception”). The fair value of the contingent consideration liability - related party was determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The fair value of the contingent milestone and royalty liabilities was estimated based on the discounted cash flow valuation technique. The technique considered the following unobservable inputs:

- market-based discount rates,
- the probability and timing of achieving the specified milestones and royalties as of each valuation date,
- the probability of executing the license agreement, and
- the expected first year of revenue.

Perception

The fair value of the Perception contingent milestone and royalty liabilities could change in future periods depending on prospects for the outcome of R-Ketamine milestone meetings with the FDA or other regulatory authorities, and whether the Company realizes a significant increase or decrease in sales upon commercialization. The most significant assumptions in the discounted cash flow valuation technique that impacts the fair value of the milestone contingent consideration are the projected milestone timing and the probability of the milestone being met. Further, significant assumptions in the discounted cash flow that impacts the fair value of the royalty contingent consideration are the projected revenue over ten years, the timing of royalties on commercial revenue, and the probability of success rate for a commercial R-Ketamine product. The valuations as of December 31, 2024 and 2023, used inputs that were unobservable inputs with the most significant being the discount rates for royalties on projected commercial revenue and clinical milestones and probability of success estimates over the following ten years, which represent Level 3 measurements within the fair value hierarchy.

The fair value of the contingent milestone and royalty liabilities for Perception was estimated to be $0.1 million and $0.6 million as of December 31, 2024 and 2023, respectively.

The fair value of the Perception contingent consideration liability - related parties was calculated using the following significant unobservable inputs:

		December 31, 2024	December 31, 2023
Valuation Technique	Significant Unobservable Inputs	Input Range	Input Range
Discounted cash flow	Milestone contingent consideration:		
	Discount rate	11.6%	13.5%
	Probability of the milestone	5.0%	28.0%
Discounted cash flow with Scenario-Based Method	Royalty contingent consideration:		
	Discount rate for royalties	3.8% - 4.3%	13.0% - 14.2%
	Discount rate for royalties on milestones	3.8% - 4.3%	13.0% - 14.2%
	Probability of success rate	5.0%	13.4% - 28.0%

Contingent Consideration Liabilities

The contingent consideration liabilities in the fair value table above relates to milestone payments in connection with the acquisition of DemeRx IB, Inc. ("DemeRx"), and TryptageniX. The fair value of the contingent consideration liabilities were determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The fair value of the contingent milestone and royalty liabilities was estimated based on the discounted cash flow valuation technique. The technique considered the following unobservable inputs:

- market-based discount rates, and
- the probability and timing of achieving the specified milestones as of each valuation date

DemeRx

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.’s equity ownership of DemeRx IB (the “Stock Purchase”), in exchange for consideration that included, among other items, earn-out consideration of up to an additional $8.0 million payable to DemeRx, Inc. contingent upon the achievement of certain development milestones directly related to DemeRx’s oral capsule formulation of ibogaine (“DMX-1002”) program. The earn-out consideration was recorded at fair value in contingent consideration as a liability under ASC 480 and the fair value is adjusted each quarter and reflected in other income and expense in the statements of operations.

The fair value of the DemeRx contingent milestone could change in future periods depending on prospects for the outcome of ibogaine milestone meetings with the FDA or other regulatory authorities. The most significant assumptions in the discounted cash flow valuation technique that impacts the fair value of the milestone contingent consideration are the projected milestone timing and the probability of the milestone being met. The valuations as of December 31, 2024 , used inputs that were unobservable inputs with the most significant being the discount rates clinical milestones and probability of success, which represent Level 3 measurements within the fair value hierarchy.

For the years ended December 31, 2024 and 2023, the fair value of the contingent milestone for DemeRx was estimated to be $0.2 million and $1.4 million, respectively.

The fair value of the DemeRx contingent consideration liability - related parties was calculated using the following significant unobservable inputs:

		December 31, 2024	December 31, 2023
Valuation Technique	Significant Unobservable Inputs	Input Range	Input Range
Discounted cash flow	Milestone contingent consideration:		
	Discount rate	11.7%-11.8%	13.9%
	Probability of the milestone	4.0% - 5.0%	20.0% - 25.0%

TryptageniX

The fair value of the contingent liability for TryptageniX was estimated to be an immaterial amount and $0.2 million as of December 31, 2024 and 2023, respectively. The contingent liability is comprised of research and development milestone success fee payments and royalties payments. The fair value of the success fee liability was estimated based on the scenario-based method within the income approach. The fair value of the contingent liability for TryptageniX was determined based on significant unobservable inputs, including the discount rate, estimated probabilities of success, and timing of achieving certain clinical milestones. The fair value of the royalties liability was determined to be de minimis as the products are in the early stages of development. The Company will continue to assess the appropriateness of the fair value of the contingent liability as the products continue through development.

Convertible Promissory Note

As described in Note 13, in December 2023 and April 2024, the Company entered into subscription agreements with each of a noteholder and a related party noteholder, respectively (together the "Subscription Agreements") whereby each of the noteholder and the related party noteholder exchanged their ATAI Life Sciences AG notes (the "Old AG Notes") into the same principal amount of new convertible notes issued by ATAI Life Sciences N.V. (the "New NV Notes"). The exchange resulted in the New NV Notes conversion option no longer meeting the equity classification criteria. Accordingly, at the time of the exchange modification, the Company bifurcated the conversion option and reclassified the conversion option fair value from equity to a liability and is included in Short-term convertible promissory notes and derivative liability and Short-term convertible promissory notes and derivative liability - related party, respectively, in the consolidated balance sheets. The conversion option is measured at fair value on a quarterly basis and any changes in the fair value will be recorded as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. For the years ended December 31, 2024 and 2023, the Company recognized a loss of $3.4 million and $0.7 million, respectively, as a result of the change in fair value of the New NV Notes.

The conversion option fair value was estimated utilizing the Black-Scholes option pricing model and is classified as Level 3 in the fair value hierarchy based on the nature of the inputs and valuation techniques. The Black-Scholes option pricing model is based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the conversion feature, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying common stock. The expected volatility is based upon the historical volatility of daily lognormal returns on atai shares.

A significant input that is included in the valuation of the conversion feature as of December 31, 2024 and December 31, 2023 is volatility of 75.0% and 78.6%, respectively.

The following table provides a roll forward of the aggregate fair values of the Company's financial instruments described above, for which fair value is determined using Level 3 inputs (in thousands):

	Beckley Psytech Additional Warrants	IntelGenx Debt [(i)]	IntelGenx Investments Held at Fair Value [(ii)]	IntelGenx Subsequent DIP Loan Commitment	Contingent Consideration Liabilities - Related Parties [(iii)]	Contingent Consideration Liabilities [(iv)]	New NV Notes Conversion Feature
Balance as of December 31, 2023	$ —	$ 11,202	$ 6,124	$ —	$ 620	$ 1,637	$ 2,385
Initial fair value of instrument	2,645	8,243	420	680	-	-	3,590
Change in fair value, including interest	1,676	(13,729)	(6,544)	—	(510)	(1,425)	(3,363)
Additional Warrants received	(1,538)	—	—	—	—	—	—
Reduction in commitment	—	—	—	(680)	—	—	—
Consideration for acquisition	—	(5,715)	—	—	—	—	—
Balance as of December 31, 2024	$ 2,783	$ —	$ —	$ —	$ 110	$ 212	$ 2,611

[(i)] Includes the IntelGenx Term Loan, the 2023 Initial Notes, the 2023 Subsequent Notes, the DIP Loan, and the 2023 Term Loan Note.

[(ii)] Includes the 2023 Initial Warrants, the 2023 Subsequent Warrants, the 2024 Warrants, and the Call Option Units.

[(iii)] Includes Perception milestone based contingent consideration liability.

[(iv)] Includes contingent consideration liability related to DemeRx IB Stock Purchase and contingent consideration liability related to the TryptageniX research and development milestone success fee payments and royalties payments.

	IntelGenx Convertible Notes Receivable	IntelGenx Investments Held at Fair Value [(i)]	Contingent Consideration Liability - Related Parties [(ii)]	Contingent Consideration Liability [(iii)]	2018 Convertible Notes Call Option
Balance as of December 31, 2022	$ —	$ —	$ 743	$ 210	$ —
Initial fair value of instrument	10,800	5,787	—	1,329	1,668
Change in fair value	(116)	105	(34)	98	717
Additional contribution	518	232	—	—	—
Extinguishment of liability	—	—	(89)	—	—
Balance as of December 31, 2023	$ 11,202	$ 6,124	$ 620	$ 1,637	$ 2,385

[i] Includes, Initial Warrants, Additional Unit Awards, 2023 Initial Warrants, 2023 Subsequent Warrants, and Call Option Units.
[ii] Includes Perception's milestone-based contingent consideration liability.
[iii] Includes the contingent consideration liability related to DemeRx IB Stock Purchase and the contingent consideration liability related to the TryptageniX research and development milestone success fee payments and royalties payments.

8. Prepaid Expenses and Other Current Assets

Prepaid expenses consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Prepaid research and development related expenses	$ 4,900	$ 1,822
Tax receivables	1,348	1,752
Other	775	846
Prepaid insurance	772	1,410
Total	$ 7,795	$ 5,830

9. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2024	December 31, 2023
Manufacturing equipment	$ 1,572	$ —
Laboratory and office equipment	236	—
Furniture and fixtures	973	1,017
Computer equipment	152	117
	$ 2,933	$ 1,134
Less: accumulated depreciation and amortization	398	153
Total	$ 2,535	$ 981

As of December 31, 2024, substantially all of the Company’s in use manufacturing equipment, laboratory and office equipment and computer equipment were located in Canada and are comprised of assets acquired with the Company's acquisition of IGX. The Company has $1.0 million of manufacturing equipment not in service located in Germany also acquired with the Company's acquisition of IGX. For the years ended December 31, 2024 and 2023, approximately $0.7 million and $0.9 million of the Company's remaining property and equipment was located in Germany, respectively, and $0.1 million and $0.1 million in the U.S, respectively.

For the years ended December 31, 2024 and 2023, depreciation and amortization expense on property and equipment was $0.2 million and $0.1 million, respectively.

10. Intangible Assets and Goodwill

Intangible Assets

Definite-lived Intangible Assets

In connection with the Company's acquisition of IGX (see Note 3 above), the Company acquired ownership and intellectual property rights to IGX's Oral Thin Film ("OTF") platform technology. This platform technology serves as the foundation and platform to deliver active pharmaceutical ingredients for both the Company's and other potential customer products. The Company determined there to be legal and competitive factors that limit the useful life of these OTF Technologies and therefore designated them as a definite-lived intangible asset.

In addition, the Company acquired a manufacturing contract with regards to IGX's right to manufacture gBelBuca, a generic version of Belbuca®, an opioid that is used to manage chronic pain severe enough to require daily, around-the-clock, long-term treatment. This manufacturing contract includes potential future royalty and milestone payments, for which the Company is now eligible to receive.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the transaction to the underlying assets acquired and liabilities assumed, based upon the estimated fair values of those assets and liabilities at the date of acquisition. The value allocated to the OTF Technology was $2.4 million, which will be amortized over the remaining estimated useful life of approximately 10 years. The value allocated to the gBelBuca contract was $0.2 million, which will be amortized over the estimated remaining useful life of approximately 19 years.

In addition to the definite-lived intangible assets above, the Company's definite-lived intangible assets also includes $0.6 million of previously capitalized internal-use software costs, which will be amortized over the estimated remaining useful life of approximately 2 years.

Indefinite-lived Intangible Assets

The Company owns various intellectual property, including in-process digital therapeutics application platforms, clinical trial data from previously consolidated or wholly-owned subsidiaries, and other intangible assets. The Company has designated each of these intangible assets to be indefinite-lived as there are no characteristics that limit each asset's useful life.

As of December 31, 2024, the Company determined they were no longer pursuing digital therapeutics as an enabling technology for their product compounds. The Company performed an impairment assessment and concluded their in-process digital therapeutics application platforms were fully impaired. The carrying value of these indefinite-lived intangible assets prior to the Company's assessment was $0.9 million. Accordingly, the Company recognized a $0.9 million impairment loss, which the Company presented as Research and development expense in the Company's consolidated statements of operations.

The Company continually evaluates whether events or circumstances have occurred that indicate that the carrying value of the intangible assets may be impaired or that the estimated remaining useful lives of these assets may warrant revision. Other than the impairment explained above, as of December 31, 2024, the Company determined that no other intangible assets were impaired and that there are no facts or circumstances that would indicate a need for changing the estimated remaining useful lives of these assets.

For the year ended December 31, 2023, the $1.8 million intangible asset balance was included in Other assets in the Company's consolidated balance sheets.

Intangible assets consisted of the following (in thousands):

		December 31, 2024				December 31, 2023		
	Remaining Useful Lives	Cost	Accumulated Amortization	Impairment	Net Carrying Amount	Cost	Accumulated Amortization	Net Carrying Amount
OTF Technology	10 years	$ 2,433	$ (57)	$ —	$ 2,376	$ —	$ —	$ —
gBelBuca manufacturing contract	19 years	192	(2)	—	190	—	—	—
Internal-use software	2 years	647	(466)	—	181	686	(329)	357
In-process research and development	indefinite-lived	1,059	—	(917)	142	959	—	959
Other	various	368	(11)	—	357	464	(8)	456
Total		$ 4,698	$ (536)	$ (917)	$ 3,246	$ 2,109	$ (337)	$ 1,772

For the years ended December 31, 2024 and 2023, amortization expense related to these intangible assets was $0.2 million and $0.2 million, respectively.

Estimated future amortization expense for intangible assets subsequent to December 31, 2024 is as follows (in thousands):

2025	$	418
2026		288
2027		249
2028		249
2029		249
Thereafter		1,234
	$	2,687

The weighted average remaining useful lives of all amortizable assets is approximately 9.9 years.

Goodwill

In connection with the Company's acquisition of IGX (see Note 3 above), the Company also recognized $0.3 million in goodwill, which was the difference between the amount of consideration associated with the transaction in excess of the fair value of net assets acquired. The goodwill is primarily attributable to the synergies of merging operations, expected future cash flows and the value of the acquired workforce. The following table presents the goodwill balances for the years ended December 31, 2024 and 2023 and the associated changes in goodwill through December 31, 2024 (in thousands).

Balance at December 31, 2023	$	—
IGX acquisition		331
Measurement period adjustments		—
Balance at December 31, 2024	$	331

11. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued payroll	$ 3,776	$ 4,941
Accrued external research and development expenses	2,479	3,031
Accrued accounting, legal, and other professional fees	2,867	5,468
Other liabilities	537	1,101
Taxes payable	188	715
Total	$ 9,847	$ 15,256

12. Leases

Operating lease Right-of-Use ("ROU") assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The operating lease ROU asset also includes lease payments made, lease incentives, and initial direct costs incurred, if any.

The Company leases certain office space under long-term operating leases that expire at various dates through 2028. The Company generally has options to renew lease terms on its facilities, which may be exercised at the Company's sole discretion.

In connection with the Company's acquisition of IGX on October 2, 2024, the Company assumed lessee rights to approximately 43,000 square feet of office, lab, and manufacturing spaces in Montréal, Canada. The leases expire in February 2026. The lease terms include an option to renew for an additional 5 years, which may be exercised at the Company's sole discretion.

The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option and has concluded on all operating leases that is it not reasonably certain that any options will be exercised.

The weighted-average remaining lease term for the Company's operating leases as of December 31, 2024 was 2.9 years. The weighted-average discount rate for the Company's operating leases as of December 31, 2024 was 12.7%.

ROU assets and lease liabilities related to the Company's operating leases are as follows (in thousands):

	Balance Sheet Classification	December 31, 2024	December 31, 2023
Right-of-use assets	Operating lease right-of-use asset, net	$ 1,334	$ 1,223
Current lease liabilities	Current portion of lease liability	477	275
Non-current lease liabilities	Non-current portion of lease liability	732	990

Expenses related to leases is recorded on a straight-line basis over the lease term. The following table summarizes lease costs by component for the year ended December 31, 2024 and 2023 (in thousands):

		For the Year Ended December 31,	
Lease Cost Components	Statements of Operations Classification	2024	2023
Operating lease cost	Operating expenses: General and administrative	$ 387	$ 663
Operating lease cost	Operating expenses: Research and Development	125	—
Short-term lease cost	Operating expenses: General and administrative	137	338
Total lease cost		$ 649	$ 1,001

Future minimum commitments under all non-cancelable operating leases are as follows (in thousands):

Year Ended		
2025	$	601
2026		391
2027		349
2028		116
2029		—
Total lease payments		1,457
Less: Imputed interest		(248)
Present value of lease liabilities	$	1,209

Supplemental cash flow information related to the Company's operating leases for the year ended December 31, 2024 and 2023 (in thousands):

	December 31, 2024	December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 436	$ 440
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 1,377

13. Debt

Convertible Promissory Notes

Convertible Promissory Notes—Related Parties

During November 2018 and October 2020, the Company executed a terms and conditions agreement (the "Convertible Note Agreement") under which it would issue convertible promissory notes to investors. An investor would become a party to the Convertible Note Agreement and would be issued a convertible promissory note by executing and delivering a subscription form. In November 2018 and October 2020, certain investors subscribed to the Convertible Note Agreement and the Company issued convertible promissory notes in the aggregate principal amount of €1.0 million or $1.2 million (collectively, the "Convertible Notes"). The Convertible Notes are non-interest-bearing, unsecured and are due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each Convertible Note has a face value of €1 and is convertible into one share of ATAI Life Sciences AG upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity, except during certain periods subsequent to the consummation of the IPO. The Convertible Notes may be declared for early redemption by the noteholders upon occurrence of specified events of default, including payment default, insolvency and a material adverse change in the Company's business, operations or financial or other condition. Upon early redemption, the conversion right with respect to the Convertible Notes may no longer be exercised.

The Company concluded that both the embedded conversion feature, which is exercisable by the investor at any time during the maturity, and the contingent put option, which would trigger upon the occurrence of an event of default of the Convertible Notes, do not meet the criteria to be bifurcated and separately accounted for as derivatives and the notes were recorded net of discount and issuance costs, or a reduction to the carrying value of the notes issued in November 2018, with a corresponding adjustment to additional paid in capital. The discount is being amortized using the effective interest method over the period from the respective date of issuance to the Maturity Date.

The Company determined that the October 2020 notes were issued in exchange for services previously provided by the Company's founders and other shareholders and were fully vested and non-forfeitable upon issuance. These instruments were therefore considered share based compensation awards to non-employees, and the instruments were initially measured and recorded at their grant date fair value based on a Black-Scholes option- pricing model. The fair value of the October 2020 notes exceeded the principal amount that will be due at maturity. Therefore, at initial recognition, the October 2020 notes were accounted for as convertible debt issued at a substantial premium, such that the face value of the note is recorded as a liability and the premium was recorded as paid-in capital.

In April 2021, the Company undertook a corporate reorganization. Upon the corporate reorganization, ATAI Life Sciences N.V became the sole shareholder of ATAI Life Sciences AG. In connection with the corporate reorganization, all former shareholders of ATAI Life Sciences AG contributed their shares of ATAI Life Sciences AG to ATAI Life Sciences N.V. and received sixteen shares in ATAI Life Sciences N.V. for every one share of ATAI Life Sciences AG. In 2023, certain November 2018 noteholders elected to convert some of their convertible promissory notes into shares of ATAI Life Sciences N.V for an immaterial amount. As of December 31, 2023, all notes issued in November 2018 have been converted and the only outstanding Convertible Notes are those issued in October 2020. As of December 31, 2024, the Convertible notes issued in October 2020 continue to be outstanding.

Exchange of Convertible Promissory Notes

In November 2023 and April 2024, a noteholder and a related party noteholder, respectively, of the Convertible Notes issued in October 2020 and ATAI Life Sciences AG executed exchange agreements (together the "Exchange Agreements") where each noteholder agreed to exchange its Convertible Notes issued by ATAI Life Sciences AG ("Old AG Notes") into the same principal amount of new convertible notes issued by ATAI Life Sciences NV ("New NV Notes"). The New NV Notes are non-interest-bearing, unsecured and are due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each New NV Note has a face value of €1 and is convertible into sixteen shares of ATAI Life Sciences NV upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity. The New NV Notes may be declared for early redemption by the noteholders upon occurrence of specified events of default, including payment default, insolvency and a material adverse change in the Company's business, operations or financial or other condition. Upon early redemption, the conversion right with respect to the New NV Notes may no longer be exercised.

In December 2023 and April 2024, the Company entered into subscription agreements with each of the noteholder and related party noteholder, respectively (together the "Subscription Agreements") and exchanged their respective Old AG Notes into New NV Notes. The Company determined that the note exchanges were modifications of the debt. The Exchange Agreements and Subscription Agreements resulted in the New NV Notes conversion option no longer meeting the equity classification criteria. Accordingly, at the time of the Exchange Agreements modification, the Company bifurcated the conversion option and reclassified the conversion option fair value from equity to a liability and is included in Convertible promissory notes and derivative liability in the consolidated balance sheets. The conversion option is measured at fair value on a quarterly basis and any changes in the fair value will be recorded as Change in fair value of assets and liabilities, net, in the consolidated statements of operations. For the years ended December 31, 2024 and 2023, the Company recognized a gain of $3.4 million and a loss of $0.7 million, respectively, as a result of the change in fair value of the New NV Notes.

For the years ended December 31, 2024 and 2023, the fair value of the Convertible Notes and derivative liability was $1.8 million and $2.7 million, respectively. For the year ended December 31, 2024, the fair value of the Short-term convertible promissory note and derivative liability - related party was $1.2 million. As of December 31, 2023, the carrying amount and fair value amount of the 2020 Convertible Notes was $0.2 million and $1.5 million, respectively.

Term Loan

Hercules Loan and Security Agreement

In August 2022 (the "Closing Date"), the Company and certain subsidiaries, as guarantors, and Hercules Capital, Inc., a Maryland corporation ("Hercules"), entered into a Loan and Security Agreement the "Hercules Loan Agreement". The Hercules Loan Agreement provides for term loans in an aggregate principal amount of up to $175.0 million under multiple tranches (as amended by that certain First Amendment to Loan and Security Agreement, dated as of March 13, 2023, the "First Amendment", that Second Amendment to Loan and Security Agreement, dated as of May 26, 2023, the "Second Amendment," and that Third Amendment to Loan and Security Agreement, dated August 14, 2024, the "Third Amendment," and collectively, the "2022 Term Loan Facility").

On May 26, 2023, the Company, ATAI Life Sciences AG ("ATAI AG" and together with the Company, the "Borrowers") and certain subsidiary guarantors of the Company (collectively, the "Subsidiary Guarantors") entered into the Second Amendment with the several banks and other financial institutions or entities from time to time parties to the Hercules Loan Agreement, defined below, (collectively, the "Lenders") and Hercules, in its capacity as administrative agent and collateral agent for itself and for the Lenders (the "Agent") which amended that certain Loan and Security Agreement, dated August 9, 2022 (as amended by the First Amendment, the "Existing Loan Agreement," and as amended by the Second Amendment, the "Hercules Loan Agreement") to, among other things, (i) extend the availability of Tranche 1B of $10.0 million, from May 1, 2023, under the Existing Loan Agreement, to November 15, 2024, (ii) extend the availability of Tranche 1C of $15.0 million, from December 15, 2023, under the Existing Loan Agreement, to December 15, 2024, (iii) provide Tranche 1D of $20.0 million, available upon the earlier of (x) the full draw of Tranche 1C and (y) the expiration of Tranche 1C availability, through February 15, 2025, (iv) extend the availability of Tranche 2 of $15.0 million, from June 30, 2024, under the Existing Loan Agreement, subject to certain conditions under the Hercules Loan Agreement, to the earlier of (x) the full draw of Tranche 1D and (y) the expiration of Tranche 1D availability, through March 15, 2025, subject to the Tranche 2 Draw Test, (v) extend the timeline to achieve the second amortization extension condition, from June 30, 2024, in the Existing Loan Agreement, to December 15, 2024, (vi) amend the Tranche 2 Draw Test, satisfaction of which is a condition to draw Tranche 2 under the Hercules Loan Agreement and (vii) extend the financial covenant commencement date, from the later of (x) July 1, 2023, and (y) the date that the outstanding debt under the facility is equal to or greater than $40.0 million, in the Existing Loan Agreement, to the later of (x) May 1, 2024, and (y) the date that the outstanding debt under the facility is equal to or greater than $30.0 million, provided, that the financial covenant is waived if the Company has a market capitalization of at least $550.0 million.

On August 14, 2024 (the "Third Amendment Date"), the Borrowers and certain Subsidiary Guarantors" entered into the Third Amendment with the Lenders and Hercules, in its capacity as the Agent, which amended that certain Loan and Security Agreement, dated August 9, 2022 (as amended by the First Amendment, the Second Amendment and the Third Amendment, the "2022 Term Loan Agreement") to, among other things, (i) provide Tranche 1B of $5.0 million on the Third Amendment Date, (ii) reduce the remainder of available Tranche 1 to $25.0 million, and extend the availability thereof (x) with respect to Tranche 1C, to be available after the Third Amendment Date until March 31, 2025, and (y) with respect to Tranche 1D, to be available upon the earlier to occur of (1) March 31, 2025 and (2) full borrowing of Tranche 1C, until June 30, 2025, (iii) increase Tranche 2 to $30.0 million, and extend the availability thereof to be available upon the earlier to occur of (1) June 30, 2025, and (2) full borrowing of Tranche 1D, until September 30, 2025, subject to the Tranche 2 Draw Test, (iv) extend the availability of Tranche 3 of $100.0 million, through March 31, 2026, available subject to lender's investment committee approval, (v) extend the amortization date to September 1, 2025, and extend the timeline to achieve the second amortization extension condition, to June 30, 2025, upon the occurrence of which the amortization date may be extended to March 1, 2026, (vi) amend the financial covenant to commence on October 1, 2024, and require that so long as the Company's market capitalization is less than $550.0 million, Borrowers shall maintain qualified cash equal to at least 50% of the sum of (x) the amount of outstanding debt under the facility plus (y) Qualified Cash A/P Amount (as defined in the Agreement), or upon the occurrence of certain conditions, 70% of the sum of (x) the amount of outstanding debt under the facility plus (y) Qualified Cash A/P Amount, and (vii) reduce the interest rate to equal the greater of (x) 9.05% or (y) prime rate plus 4.30% (or, upon achieving certain conditions, (y) shall equal prime rate plus 4.05%).

The 2022 Term Loan Facility will mature on August 1, 2026 (the "Maturity Date"), which may be extended until February 1, 2027 if the Company raises at least $175.0 million of unrestricted new net cash proceeds from certain permitted sources after the Closing Date and prior to June 30, 2025, and satisfies certain other specified conditions (the "Extension Condition Two"). The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) the prime rate as reported in the Wall Street Journal plus 4.30% and (ii) 9.05%; provided, that if the Extension Condition Two is satisfied, the rate of interest in the foregoing clause (i) is prime rate as reported in The Wall Street Journal plus 4.05%. Accrued interest is payable monthly following the funding of each term loan advance. The Company may make payments of interest only, without any loan amortization payments, until September 1, 2025, which date may be extended to (i) March 1, 2026 if Extension Condition Two is achieved. At the end of the interest

only period, the Company is required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly installments.

The 2022 Term Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent (the "Qualified Cash") at all times commencing from the Closing Date, which includes a cap on the amount of cash that can be held by, among others, certain of our foreign subsidiaries in Australia and the United Kingdom. In addition, the financial covenant under the 2022 Term Loan Agreement requires that beginning on October 1, 2024, the Company shall maintain Qualified Cash in an amount no less than the sum of (1) 50% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that have not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, upon the occurrence of certain conditions, the Company shall at all times maintain Qualified cash in an amount no less than the sum of (1) 70% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that have not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, further, that the financial covenant shall not apply on any day that the Company's market capitalization is at least $550.0 million measured on a consecutive 10-business day period immediately prior to such date of measurement and tested on a daily basis. Upon the occurrence of an event of default, including a material adverse effect, subject to certain exceptions, on the Company and ATAI AG's, taken together, business, operations, properties, assets or financial condition, and subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by the Lenders. As of December 31, 2024, the Company was in compliance with all applicable covenants under the Hercules Loan Agreement.

In addition, the Company is required to make a final payment fee (the "End of Term Charge") upon the earlier of (i) the Maturity Date, (ii) the date that the Company prepays, in full or in part, the principal balance of the 2022 Term Loan Facility, or (iii) the date that the outstanding balance of the 2022 Term Loan Facility becomes due and payable. The End of Term Charge is 6.95% of the aggregate principal amount of the term loans so repaid or prepaid under the 2022 Term Loan Agreement.

The Company may, at its option, prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.00% of the principal amount prepaid if the prepayment occurs on or prior to the first anniversary of the Closing Date, (ii) 1.0% of the principal amount prepaid if the prepayment occurs after the first anniversary and on or prior to the second anniversary of the Closing Date, and (iii) 0.5% of the principal amount prepaid if the prepayment occurs after the second anniversary and prior to the Maturity Date.

The Company incurred financing expenses related to the Hercules Loan Agreement, which are recorded as an offset to long-term debt on the Company's consolidated balance sheets. These deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in other income, net in the Company's consolidated statements of operations. During the years ended December 31, 2024 and 2023, respectively, interest expense included $0.5 million and $0.4 million of amortized deferred financing costs related to the 2022 Term Loan Facility, respectively.

Outstanding debt obligations are as follows (in thousands):

	December 31, 2024	December 31, 2023
Principal amount	$ 20,000	$ 15,000
End of the term charge	1,390	1,042
Less: unamortized issuance discount	(123)	(204)
Less: unamortized issuance costs	(51)	(84)
Less: unamortized end of term charge	(709)	(707)
Net carrying amount	20,507	15,047
Less: current maturities	(6,374)	—
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 14,133	$ 15,047

For the years ended December 31, 2024 and 2023, the fair value of the outstanding Hercules debt obligations was $21.5 million and $16.2 million, respectively. The fair value of the Hercules debt obligations represent Level 3 measurements within the fair value hierarchy.

14. Common Stock

All common shareholders have identical rights. Each common share entitles the holder to one vote on all matters submitted to the shareholders for a vote.

All holders of common shares are entitled to receive dividends, as may be declared by the Company's supervisory board. Upon liquidation, common shareholders will receive distribution on a pro rata basis. As of December 31, 2024 and December 31, 2023, no cash dividends have been declared or paid.

In November 2022, the Company entered into an Open Market Sale Agreement with Jefferies LLC ("Jefferies"), pursuant to which the Company may issue and sell its common shares, nominal value €0.10 per share, having an aggregate offering price of up to $150.0 million, from time to time through an "at the market" equity offering program under which Jefferies will act as sales agent. There have been no sales under the Sales Agreement for the years ended December 31, 2024 and 2023.

15. Stock-Based Compensation

atai Equity Incentive Plans

The Company has stock options and restricted stock units ("RSUs") outstanding under various equity incentive plans, including the 2021 Incentive Plan, 2020 Incentive Plan, and HSOP Plan (all as defined below).

Atai Life Sciences 2021 Incentive Award Plan

Effective April 23, 2021, the Company adopted and the atai shareholders approved the 2021 Incentive Award Plan ("2021 Incentive Plan"). The 2021 Incentive Plan is administered by the Company's supervisory board. The plan is intended to encourage ownership of shares by employees, directors, and certain consultants to the Company in order to attract and retain such individuals, to induce them to work for the benefit of the Company or of an affiliate and to provide additional incentive for them to promote the success of the Company. The 2021 Incentive Plan enables the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to executive officers, directors and other employees and consultants of the Company.

The Company has reserved up to 63,336,909 shares of common stock, for issuance to executive officers, directors and employees and consultants of the Company pursuant to the 2021 Incentive Plan. In accordance with the evergreen clause in the Company's 2021 Incentive Plan, the number of shares initially available for issuance was increased by 8,296,796 and 8,301,319 shares of common stock effective January 1, 2023 and 2024, respectively. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. As of December 31, 2024, 42,963,222 shares were available for future grants under the 2021 Incentive Plan.

Atai Life Sciences 2020 Equity Incentive Plan

Prior to the effective date of the 2021 Incentive Plan, the Company granted equity awards to eligible executive officers, directors, employees and consultants of the Company under the 2020 Employee, Director and Consultant Equity Incentive Plan (as amended from time to time, "2020 Incentive Plan"). As of the effective date of the 2021 Incentive Plan, the Company has not granted any further awards under the 2020 Incentive Plan.

As of December 31, 2024, there were no shares available for future grants under the 2020 Incentive Plan and any shares subject to outstanding stock options originally granted under the 2020 Incentive Plan that terminate, expire or lapse for any reason without the delivery of shares to the holder thereof shall become available for issuance pursuant to the 2021 Incentive

In October 2024, the Company modified all outstanding pre-IPO stock options under the 2020 Equity Incentive Plan to extend the contractual term to be ten years, to align with stock options granted under the 2021 Incentive Plan, which is consistent with prevailing market practices. The Company recognized approximately $3.2 million in non-cash stock-based compensation expense related to this modification, including $2.0 million of research and development expenses and $1.2 million of general and administrative expenses.

Stock Options

The stock options outstanding below consist primarily of both service and performance-based options to purchase common shares of the Company. These stock options have a ten-year contractual term. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The following is a summary of stock option activity from December 31, 2023 to December 31, 2024:

	Number of Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding as of December 31, 2023	39,066,454		$ 4.62	5.56	$ 6,294
Granted	11,411,894	[i]	1.71	—	—
Exercised	(453,043)		1.93	—	—
Cancelled or forfeited	(9,982,384)		4.78	—	—
Outstanding as of December 31, 2024	40,042,921	[ii]	$ 3.81	7.29	$ 5,119
Options exercisable as of December 31, 2024	24,312,752		$ 4.66	6.52	$ 4,558

[i] Includes (a) 7,757,000 stock options with 25% vesting on January 1, 2025 and the remaining over a three-year service period, (b) 1,016,094 stock options that will vest upon the satisfaction of specified market-based conditions tied to the price of the Company's publicly traded shares, (c) 1,711,800 stock options that will vest over a four-year service period, (d) 515,000 stock options that will vest after a one-year service period, and (e) 412,000 stock options with 33% vesting on the first anniversary of the grant date and the remaining over a two-year service period.

[ii] Includes 15,730,170 outstanding unvested stock options; (a) 7,574,659 that will continue to vest over a one to four-year service period, (b) 6,046,762 options with 25% vesting on January 1, 2025 and the remaining over a three-year service period, (c) 1,016,094 stock options that will vest upon the satisfaction of specified market-based conditions tied to the price of the Company's publicly traded shares, (d) 992,654 that will continue to vest over a three to four-year service period and upon the satisfaction of specified performance-based vesting conditions, and (e) 100,000 stock options that will continue to vest over a two-year service period and upon the satisfaction of specified market-based conditions tied to the price of the Company's publicly traded shares.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2024 and 2023 was $1.35 and $1.02, respectively.

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. For the years ended December 31, 2024 and 2023, the assumptions used in the Black-Scholes option pricing model were as follows:

	December 31,	
	2024	2023
Weighted average expected term in years	5.95	6.23
Weighted average expected stock price volatility	95.7%	85.7%
Risk-free interest rate	3.53% - 4.40%	3.50% - 4.18%
Expected dividend yield	0%	0%

For the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense related to stock options of $23.5 million and $27.9 million, respectively.

As of December 31, 2024, total unrecognized compensation cost related to the unvested stock options was $19.2 million, which is expected to be recognized over a weighted average period of 2.29 years.

Restricted Stock Units

The Company has granted RSUs to certain of its employees under the 2021 Incentive Plan, as part of its equity compensation program. Pursuant to the terms of the applicable award agreements, each RSU represents the right to receive one share of the Company’s common stock. The restricted stock units noted below consist of service-based awards vesting over a two-year period, subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company. The Company reflects restricted stock units as issued and outstanding common stock when vested and the shares have been delivered to the individual.

The following is a summary of restricted stock unit activity from December 31, 2023 to December 31, 2024:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	2,944,935	$ 1.18
Granted	—	—
Vested	1,830,313	1.18
Forfeited	395,065	1.18
Unvested at December 31, 2024	719,557	$ 1.18

For the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense related to restricted stock units of $1.8 million and $1.4 million, respectively.

The total fair value of restricted stock units vested during the year ended December 31, 2024 was $2.2 million. As of December 31, 2024, total unrecognized compensation cost related to the unvested restricted stock units was $0.2 million, which is expected to be recognized over a weighted average period of 0.20 years.

Atai Life Sciences Hurdle Share Option Plan

On August 21, 2020, the Partnership (as defined below) approved and implemented an employee stock option plan for selected executives, employees, and consultants of the Partnership (the "Hurdle Share Options Program" or the “HSOP Plan”), which became effective on January 2, 2021, the date the first grants under the HSOP Plan were made (“HSOP Options”). This plan is primarily aimed at German-based executives, employees, and consultants of the Company (collectively as “HSOP Participants”). The purpose of the HSOP Plan is to permit these individuals to indirectly participate in the appreciation in value of the Company through a German law private partnership, ATAI Life Sciences HSOP GbR (the “Partnership”). The HSOP Plan was established under the Partnership Agreement of the Partnership. The HSOP Plan requires the exercise price to be equal to the fair value of the shares on the date of grant.

The Partnership acquired 7,281,376 shares of atai common stock (“HSOP Shares”) pursuant to the HSOP Plan. HSOP Options that are canceled or forfeited without having been fully exercised will be available for future awards. As of December 31, 2024, 257,419 HSOP Options were available for future grants under the HSOP Plan.

The HSOP Plan mimics the economics of a typical stock option plan, however, with the HSOP Shares to which the HSOP Options refer already being issued to the Partnership. Each HSOP Option contains both service and performance-based vesting conditions, including a liquidity-based condition, and gives the holder the option to request the distribution of HSOP Shares under its vested HSOP Options. The grantee is required to pay a nominal value (€0.06 per share) for the shares upon grant (“Nominal Upfront Payment”). The nominal amount paid at the grant date is refundable if the HSOP Options do not vest or are forfeited. Otherwise, the nominal amount is refundable until the later of the occurrence of a Liquidity Event (as defined in the “HSOP Plan”) or the exercise date.

The HSOP Shares issued under the HSOP Plan to the Partnership are indirectly owned by HSOP Participants (being the holders of HSOP Options) via their interest in the Partnership. However, each HSOP Participant signed a nonrevocable power of attorney ceding virtually all rights and decisions, including their rights as shareholders to the Managing Partner (as defined in the Partnership agreement) of the Partnership. HSOP Participants have a forfeitable right to distributions until the HSOP Options vest, at which time the right becomes nonforfeitable. Accordingly, the HSOP Shares issued to the Partnership and allocated to the HSOP Options holders are not considered outstanding for accounting purposes. Therefore, the Company accounted for the Nominal Upfront Payment as an in-substance early exercise provision under ASC 718 as the nominal amount is deducted from the exercise price upon exercise. As of December 31, 2024, the $0.5 million Nominal Upfront Payment was recorded as an Other liability on the consolidated balance sheets. The HSOP Options include a provision that requires the HSOP Options holders pay compensation equal to 2% per annum interest on the unpaid exercise price less the €0.06 nominal amount paid upon grant (“Non-recourse Loan”) upon qualifying events (as defined in the Partnership agreement).

The 2% per annum interest rate is fixed and not linked to something other than a service, performance, or market condition, therefore, the Company accounted for the fixed rate interest charge as an in-substance non-recourse loan in a stock compensation arrangement under ASC 718. In such cases, the rights and obligations embodied in a transfer of equity shares to an employee for a note that provides no recourse to other assets or the employee (other than the correlating shares) are substantially the same as those embodied in a grant of share options. The 2% per annum interest was considered in the valuation of the HSOP Options.

HSOP Options

The HSOP Options outstanding noted below consist of service and performance-based options to request the distribution of HSOP Shares. These HSOP Options have a fifteen-year contractual term. These HSOP Options vest over a three to four-year service period, only if and when a “Liquidity Event” (as defined in the Partnership agreement) occurs within fifteen years of the date of grant. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The liquidity-based performance condition contingent upon the achievement of a Liquidity Event was satisfied in June of 2021, therefore, the Company began recognizing expense for all associated options that were previously deemed improbable of vesting.

The following is a summary of stock option activity under the HSOP Plan from December 31, 2023 to December 31, 2024:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding as of December 31, 2023	6,921,829	$ 6.64	12.01	$ —
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled or forfeited	—	—	—	—
Outstanding as of December 31, 2024	6,921,829	$ 6.64	11.01	$ —
Options exercisable as of December 31, 2024	6,921,829	$ 6.64	11.01	$ —

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. As shown above, the Company did not grant any new HSOP options during the year ended December 31, 2024 or 2023. For the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense related to HSOP Options of $0.1 million and $3.1 million, respectively.

As of December 31, 2024, there was no unrecognized compensation cost related to any unvested HSOP Options.

Subsidiary Equity Incentive Plans

Certain controlled subsidiaries of the Company adopt their own equity incentive plan ("EIP"). Each EIP is generally structured so that the applicable subsidiary, and its affiliates' employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options and restricted stock unit awards under their respective EIP. Standard option grants have time-based vesting requirements, generally vesting over a period of four years with a contractual term of ten years. Such time-based stock options use the Black-Scholes option pricing model to determine grant date fair value.

For the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense of $0.2 million and $0.5 million, respectively, in relation to subsidiary EIPs. As of December 31, 2024, there was an immaterial amount of total unrecognized stock-based compensation expense related to unvested EIP awards to employees and non-employee directors expected to be recognized over a weighted-average period of approximately 1.08 years.

Stock-Based Compensation

Stock-based compensation expense is allocated to either Research and development or General and administrative expense on the consolidated statements of operations based on the cost center to which the option holder belongs.

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2024 (in thousands):

	For the year ended December 31, 2024			
	atai 2020 and 2021 Incentive Plans	atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ 10,247	$ —	$ 150	$ 10,397
General and administrative	14,963	117	13	$ 15,093
Total stock-based compensation expense	$ 25,210	$ 117	$ 163	$ 25,490

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2023 (in thousands):

	For the year ended December 31, 2023			
	atai 2020 and 2021 Incentive Plans	atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ 12,262	$ —	$ 426	$ 12,688
General and administrative	17,203	3,052	39	$ 20,294
Total stock-based compensation expense	$ 29,465	$ 3,052	$ 465	$ 32,982

16. Income Taxes

The component of German and overseas income (loss) from continuing operations before income taxes is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Germany	$ (95,551)	$ 19,916
International	(52,854)	(59,201)
Total loss before income taxes and loss from equity method investments	$ (148,405)	$ (39,285)

The tax benefit from (provision for) income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2024	2023
Current income tax benefit (provision):		
Germany	$ —	$ —
International	356	(1,016)
Total current income tax provision:	$ 356	$ (1,016)

The international current tax provision for December 31, 2024 and 2023 is primarily comprised of corporate income taxes incurred in the United States, United Kingdom and Australia.

A reconciliation of the statutory income tax rate to the Company's effective income tax rate for continuing operations is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Loss before income taxes:		
Germany	$ (96,160)	$ 19,916
International	(52,245)	(59,201)
Total loss before income taxes:	(148,405)	(39,286)
German statutory rate	30.18%	30.18%
Expected income tax expense (benefit)	(44,781)	(11,856)
US state income taxes, net of US federal tax benefit	$ (1,010)	$ (3,662)
International tax rate differential	4,589	5,188
Effect of Australian R&D tax credit incentives	(134)	582
Effect of consolidation and deconsolidation of subsidiaries	88	3,250
Effect of share-based compensation expense	305	975
Effect of statutory to US GAAP accounting adjustments	—	—
Compensation Expenses not deductible under IRC Section 162(m)	975	1,368
Expenses not deductible for tax purposes	525	600
Return to Provision and deferred tax adjustments	(10,438)	10,188
Uncertain Tax Positions	(22)	96
Change in German and International valuation allowance	49,547	(5,713)
Total income tax expense	$ (356)	$ 1,016
Effective income tax rate:	0.24%	-2.59%

The Company is headquartered in Berlin, Germany and has subsidiaries in the United States, Australia, the United Kingdom, and Canada as well as minority investments in Canada, Germany, and the United Kingdom. The Company incurred tax losses in most jurisdictions, however, generated taxable profits in certain United States subsidiaries, United Kingdom, and Australian subsidiaries. The weighted-average combined German corporate income tax rate for the year ended December 31, 2024 and 2023 was 30.18% (inclusive a corporate income tax rate of 15.00%, solidarity surcharge of 0.83%, and trade tax rate of 14.35%). The weighted-average United States corporate income tax rate for year ended December 31, 2024 and 2023 was 21.00%. The weighted-average Australia corporate income tax rate for the year ended December 31, 2024 and 2023 was 25.00%. In 2024, atai Therapeutics Pty Ltd, atai Life Sciences Australia Pty ltd, Kures Australia Pty Ltd. and Empathbio Australia Pty Ltd. would not qualify for the reduced rate under the base rate entity ("BRE") test as the amount of passive income exceed 90% of total income. This entity was therefore subject to a 30% tax rate. The weighted-average United Kingdom corporate income tax rate for the year ended December 31, 2024 and 2023 was 25.00%, respectively. The combined Canada federal and provincial corporate income tax rate for the year ended December 31, 2024 was 26.5%.

Deferred income taxes are provided for the effects of temporary differences between the amounts of assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax purposes.

Significant components of deferred tax assets and deferred tax liabilities consisted of the following (in thousands):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
German tax loss carryforward	$ 55,507	$ 49,014
International tax loss carryforward	26,869	16,270
Share compensation	39,975	35,062
Capitalized research and experimentation expenses	31,010	19,312
Operating lease right-of-use liability	—	13
Other deductible timing differences	1,300	1,127
Total deferred tax assets, gross	154,661	120,798
Valuation allowance	(139,514)	(89,968)
Total deferred tax assets, net	$ 15,147	$ 30,830
Deferred tax liabilities:		
Fixed and intangible assets	$ (1,626)	$ (930)
Unrealized foreign exchange	(6,571)	(4,904)
Outside basis differences in equity and other investments	(2)	(2)
Investments	(6,948)	(24,982)
Operating lease right-of-use asset	—	(12)
Total deferred tax liabilities	(15,147)	(30,830)
Total deferred tax asset	$ —	$ —

The valuation allowance provided against net deferred tax assets as of December 31, 2024 and 2023 was $139.5 million and $90.0 million, respectively. The valuation allowance recorded at both periods was primarily related to German and international tax loss carryforwards, capitalized research and experimental costs, and stock-based compensation timing differences that, in the judgment of management, are not more-likely-than-not, to be realized. In 2023, a valuation allowance was provided against net deferred tax assets recognized with regard to certain subsidiaries in the United States and United Kingdom where in the judgment of management, are not more-likely-than-not to be realized as a result of a change in tax and finance policies.

As relevant to certain United States subsidiaries, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize certain research and experimental (“R&D”) expenditures under Internal Revenue Code ("IRC") Section 174 for tax years beginning after December 31, 2021 resulting in the capitalization of certain R&D costs within the Company's tax provision in 2024 and 2023. IRC Section 174 costs attributable to R&D performed in the United States and outside of the United States is amortizable over 5 years and 15 years, respectively. The majority of the Company's R&D costs incurred in 2024 and 2023 was performed outside of the United States and are amortizable over a 15 year period.

In assessing the realizability of deferred tax assets, the Company regularly considers whether it is more-likely-than-not that some or all of the recorded deferred tax assets will be realized. The future realization of deferred tax assets is subject to the existence of sufficient taxable income of the appropriate character (e.g., ordinary income or capital gain) as provided under the carryforward provisions of local tax law. Additionally, deferred tax assets with respect to tax losses in the United States may be subject to limitation as a result of ownership changes within the meaning of Section 382 of the IRC. The Company considers its limited history and historical tax losses, future projected taxable income, including the character and jurisdiction of such income, the scheduled reversal of deferred tax liabilities (including the effect in available carryback and carryforward periods), and tax-planning strategies in making this assessment. In the event that there is a change in the ability to recover deferred tax assets, the Company's income tax provision would increase or decrease in the period in which the assessment is changed.

A Section 382 analysis was undertaken in 2021, which determined that the tax loss carryforwards recorded by one United States subsidiary were able to be utilized in full, offsetting the entity's United States taxable income generated for the year ended December 31, 2021, subject to statutory limitations.

The Company has limited prior earnings history and, due to the early stages of its development and research activities, is expected to generate losses for the next several years and cannot accurately estimate future profit projections beyond such time. As such, management believes that it is more likely than not that the Company will not realize the benefits of such tax loss carryforwards and deductible differences.

As of December 31, 2024 and 2023 the Company did not have any significant unremitted earnings in its foreign subsidiaries.

The Company’s gross tax loss carryforward for tax return purposes are as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Germany tax losses	$ 183,952	$ 162,436
International tax losses	97,985	56,691
Total	$ 281,937	$ 219,127

The Company's tax loss carryforwards have an indefinite carryforward period, however, for tax years 2021 and beyond, in the United States, utilization of certain tax losses may not exceed 80% of United States taxable income in any one year, computed without regard a deduction for tax losses utilized.

The Company's 2020 through 2023 tax returns are currently open to audit. The 2021 tax return for Perception Neuroscience Holdings, Inc. was under routine audit by the Internal Revenue Service and was settled in 2024. The Company is not under examination for any other entity.

Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. As of December 31, 2024 and 2023, the Company notes the following unrecognized tax benefits.

	Year Ended December 31,	
	2024	2023
Beginning of year balance	$ 369	$ —
Decreases - prior year tax positions	(369)	—
Increases - current year tax positions	—	369
Ending of year balance	$ —	$ 369

The balances of unrecognized tax benefits as of December 31, 2024 were written down as the company has settled the 2021 audit.

17. Net Loss Per Share

Basic and diluted net loss per share attributable to atai stockholders were calculated as follows (in thousands, except share and per share data):

	For the year ended December 31,	
	2024	2023
Basic and Diluted EPS		
Numerator:		
Net loss	$ (150,049)	$ (43,895)
Net loss attributable to noncontrolling interests	(780)	(3,671)
Net loss attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (149,269)	$ (40,224)
Denominator:		
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. Stockholders - basic and diluted	160,159,983	158,833,785
Net loss per share attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (0.93)	$ (0.25)

HSOP Shares issued to the Partnership and allocated to the HSOP Participants are not considered outstanding for accounting purposes and not included in the calculation of basic weighted average common shares outstanding in the table above because the HSOP Participants have a forfeitable right to distributions until the HSOP Options vest and are exercised, at which time the right becomes nonforfeitable.

The following also represents the maximum amount of outstanding shares of potentially dilutive securities that were excluded from the computation of diluted net loss per share attributable to common shareholders for the periods presented because including them would have been antidilutive:

Potentially dilutive securities to the Company's common shares:

	As of December 31,	
	2024	2023
Options to purchase common stock	40,042,921	39,066,454
HSOP options to purchase common stock	6,921,829	6,921,829
2018 short-term convertible promissory notes - related parties	2,367,200	2,367,200
2018 short-term convertible promissory notes	3,818,704	3,818,704
Unvested restricted stock units	719,557	2,944,935
	53,870,211	55,119,122

18. Commitments and Contingencies

Research and Development Agreements

The Company may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes.

Indemnification

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, supervisory board members, officers and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with supervisory directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as supervisory directors, officers or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's consolidated financial statements.

The Company also maintains director and officer insurance, which may cover certain liabilities arising from its obligation to indemnify the Company's directors. To date, the Company has not incurred any material costs and has not accrued any liabilities in the consolidated financial statements as a result of these provisions.

Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company is unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss and accordingly has not accrued a related liability. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company accrues a liability when a loss is considered probable and the amount can be reasonably estimated. When a material loss contingency is reasonably possible but not probable, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can be made. Legal fees are expensed as incurred. Given that such proceedings are subject to uncertainty, there can be no assurance that such legal proceedings, either individually or in the aggregate, will not have a material adverse effect on our business, results of operations, financial condition or cash flows.

19. License Agreements

Otsuka License and Collaboration Agreement

In March 2021, Perception entered into a license and collaboration agreement (the "Otsuka Agreement") with Otsuka under which Perception granted exclusive rights to Otsuka to develop and commercialize products containing arketamine, known as PCN-101 in Japan for the treatment of any depression, including treatment-resistant depression, or major depressive disorder or any of their related symptoms or conditions at its own cost and expense. Perception retained all rights to PCN-101 outside of Japan.

With the execution of the Otsuka Agreement, Perception received an upfront, non-refundable payment of $20.0 million. Perception is also entitled to receive aggregate payments of up to $35.0 million if certain development and regulatory milestones are achieved for the current or a new intravenous formulation of a product and up to $66.0 million in commercial milestones upon the achievement of certain commercial sales thresholds. Otsuka is obligated to pay Perception a tiered, double-digit royalty on net sales of products containing PCN-101 in Japan, subject to reduction in certain circumstances. In January 2025, Otsuka provided a notice of termination pursuant to the Otsuka Agreement, effective April 24, 2025. Following the effective termination date, the Company will no longer be eligible to receive any milestone payments or royalties pursuant to the Otsuka Agreement.

For the years ended December 31, 2024 and 2023, there were no additional milestones achieved under the Otsuka Agreement. The Company recognized revenues of $0.3 million and $0.3 million related to certain research and development services during the years ended December 31, 2024 and 2023, respectively.

National University Corporation Chiba University License Agreement

In August 2017, Perception entered into a license agreement (the "CHIBA License"), with the National University Corporation Chiba University or CHIBA, relating to Perception's drug discovery and development initiatives. Under the CHIBA License, Perception has been granted a worldwide exclusive license under certain patents and know-how of CHIBA to research, develop, manufacture, use and commercialize therapeutic products. Perception paid an upfront license fee which was recorded as research and development expense during the year ended December 31, 2017. The Company previously exercised an option and purchased licenses to additional CHIBA technologies and related know-how, and as such the Company is required to pay an annual maintenance fee until the filing of a new drug application with the Food and Drug Administration. In addition, Perception is also required to pay tiered royalties ranging in the low to mid-single-digit on future net sales of licensed products that are covered by a valid claim of a licensed patent, if any. In addition, the Company is obligated to make contingent milestone payments totaling up to $1.2 million upon the achievement of certain clinical or regulatory milestones for each of the first two licensed products and $1.0 million upon the achievement of certain clinical or regulatory milestones for each additional licensed product.

The Company has the right to terminate the CHIBA License for any reason upon a 90-day notice and if CHIBA materially breaches the agreement and fails to remedy any such default within specified cure periods. CHIBA has the right to terminate the CHIBA License if the Company declares bankruptcy, becomes insolvent or otherwise materially breaches the agreement and fails to remedy any such default within specified cure periods. Such termination does not preclude CHIBA's rights to any milestone payments, royalties, and other payments described above. The CHIBA License will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2024 and 2023, respectively, the Company did not make any material payments pursuant to the CHIBA License.

Allergan License Agreement

In February 2020, Recognify entered into an amended and restated license agreement (the "Allergan License Agreement"), with Allergan Sales, LLC, or Allergan, under which Allergan granted Recognify an exclusive (non-exclusive as to know-how), sublicensable and worldwide license under certain patent rights and know-how controlled by Allergan to develop, manufacture and commercialize certain products for use in all fields including the treatment of certain diseases and conditions of the central nervous system.

Under the Allergan License Agreement, Recognify is subject to certain diligence obligations and is obligated to use commercially reasonable efforts, either by itself or through its affiliates or sublicensees, to develop, obtain regulatory approvals for and commercialize certain licensed products, at its sole cost. If Recognify decides to enter into negotiation of a change of control transaction with any third parties or receives a proposal from a third party for such transaction, Allergan has a right of first negotiation to negotiate the terms and conditions for acquisition of Recognify or its assets.

As partial consideration for the rights granted by Allergan to Recognify under the Allergan License Agreement, Recognify paid Allergan an upfront payment of $0.5 million which was paid prior to the Company's acquisition of Recognify in November 2020. Recognify is also responsible for paying Allergan a mid-single-digit royalty on the net sales of the licensed products. In addition, Recognify is obligated to pay Allergan a low teen percentage of the non-royalty sublicense payments it receives from a third party receiving a sublicense to practice the rights licensed to Recognify under the Allergan License Agreement. Upon the occurrence of certain change of control transactions involving Recognify, or sale, assignment or transfer (other than sublicense) to a third party of any rights licensed to Recognify under the

Allergan License Agreement, Recognify is required to share with Allergan a low teen percentage of the proceeds it receives from such transactions.

Recognify has the right to terminate the Allergan License Agreement for any reason, subject to a specified notice period, and if Allergan materially breaches the agreement and fails to remedy any such default within specified cure periods. Allergan has the right to terminate the Allergan License Agreement if Recognify declares bankruptcy, becomes insolvent or otherwise materially breaches the agreement and fails to remedy any such default within the specified cure periods. Such termination does not preclude Allergan's rights to any milestone payments, royalties, or other payments described above. The Allergan License Agreement will remain in effect until terminated by the parties according to their rights.

During the years ended December 31, 2024 and 2023, respectively, the Company did not make any material payments pursuant to the Allergan License Agreement.

Columbia Stock Purchase and License Agreement

In June 2020, Kures entered into a license agreement (the "License Agreement") with Trustees of Columbia University ("Columbia"), pursuant to which, Kures obtained an exclusive license under certain patents and technical information to discover, develop, manufacture, use and commercialize such patents or other products in all uses and applications ("Columbia IP"). In addition, in consideration for the rights to the Columbia IP, Kures entered into a Stock Purchase Agreement (the "SPA") with Columbia in contemplation of the License Agreement. Pursuant to the SPA, Kures issued to Columbia certain shares of the Kures' capital stock, representing 5.0% of Kures common stock on a fully diluted basis. Furthermore, the SPA provided that from time to time, Kures shall issue to Columbia additional shares of Kures' common stock, at a per share price equal to the then fair market value of each such share, which price shall be deemed to have been paid in partial consideration for the execution, delivery and performance by Columbia of the License Agreement, such that the common stock held by Columbia shall equal to 5.0% of the common stock on a fully diluted basis, at all times up to and through the achievement of certain funding threshold.

In April 2022, Kures issued shares of Series A-2 Preferred Stock to certain investors upon the achievement of Series A-2 milestone events. Accordingly, the Company issued certain anti-dilution common stock to Columbia worth $0.3 million. The Company expensed the cost incurred for acquiring license as acquired in-process research and development expense at inception. Since, the additional anti-dilution shares were issued as partial consideration towards the same license arrangement, the $0.4 million cost of such additional share was also expensed as acquired in-process research and development expense during the year ended December 31, 2022.

In October 2024, in connection with the dissolution of Kures, Inc., Kures and Columbia mutually agreed to terminate the existing License Agreement ("the Termination Agreement"). Under the Termination Agreement, Kures assigned to Columbia all of Kures' intellectual property rights that were filed during the term of the License Agreement and agreed that all licenses granted to Kures by Columbia are terminated. In exchange, Kures received consideration through the relief and discharge of an immaterial amount of outstanding payment obligations due to Columbia.

During the years ended December 31, 2024 and 2023, Kures did not make any material payments in connection with the Columbia agreement.

Dalriada License Agreement

In December 2021, Invyxis, Inc., or Invyxis, entered into an exclusive services and license agreement (the "Dalriada License Agreement") with Dalriada Drug Discovery Inc. ("Dalriada"). Under the Dalriada License Agreement, Dalriada is to exclusively collaborate with Invyxis to develop products, services and processes with the specific purpose of generating products consisting of new chemical entities. Invyxis will pay Dalriada up to $12.8 million in service fees for research and support services. In May 2023, the Company executed an amendment to Dalriada License Agreement, which reduced the amount Invyxis will pay Dalriada in service fees to $7.4 million. In addition, Invyxis will pay Dalriada development milestone payments and low single digit royalty payments based on net product sales. The Company has the right, but not the obligation, to settle future royalty payments based on net product sales with the our common shares. Invyxis, our wholly-owned subsidiary, and Dalriada will determine the equity settlement based on a price per share determined by both parties.

In December 2022, the Company executed an amendment to the Dalriada License Agreement, which reduced the upfront deposit from $1.1 million to $0.5 million. As such, the remaining $0.6 million was applied against research and development expense incurred. The Company will expense the remaining deposit as the services are performed as a component of research and development expense in the consolidated statements of operations.

During the years ended December 31, 2024 and 2023, the Company recorded $0.4 and $2.0 million, respectively as research and development expense. During the years ended December 31, 2024 and 2023 Invyxis made no other service fee payments to Dalriada.

20. Related Party Transactions

atai Formation

In connection with the formation of atai in 2018, the Company entered into a series of transactions with its shareholders, Apeiron, Galaxy Group Investments LLC. (“Galaxy”) and HCS Beteiligungsgesellschaft mbH (“HCS”) whereby these shareholders contributed their investments in COMPASS, Innoplexus and Juvenescence to the Company in exchange for atai’s common stock of equivalent value. Apeiron is the family office of the Company’s founder who owns 20.1% and 19.7% of the outstanding common stock in the Company as of December 31, 2024 and 2023, respectively.

Consulting Agreement with Mr. Angermayer

In January 2021, the Company entered into a consulting agreement, (the “2021 Consulting Agreement”), with Mr. Angermayer, one of the Company’s co-founders and supervisory director. Apeiron is the family office and merchant banking business of Mr. Angermayer. Pursuant to the Consulting Agreement, Mr. Angermayer agreed to render services to the Company on business and financing strategies in exchange for 624,000 shares under the 2020 Incentive Plan upon achievement of certain performance targets.

In January 2024, the Company and Mr. Angermayer entered into the Termination and New Consultancy Agreement (the “2024 Consultancy Agreement"). Pursuant to the 2024 Consultancy Agreement, the parties agreed to terminate the 2021 Consulting Agreement (as defined above) between ATAI AG and Mr. Angermayer and enter into a new consultancy agreement between the Company and Mr. Angermayer to, among other things, extend the term of the 2021 Consultancy Agreement to January 5, 2028, increase the services to include various business objectives (including related to business and finance, communication and investor relations), and provide for the grant of an option to purchase 1,658,094 shares of the Company that vests over four years in part based on continued service and in part based on the Company's total shareholder return compared to the four-year total shareholder return of the companies comprising the XBI.

As a result of the 2024 Consulting Agreement, for the year ended December 31, 2024, the Company recognized $0.4 million of stock-based compensation included in general and administrative expense in its consolidated statements of operations. Additionally, as a result of the Consulting Agreement, for the year ended December 31, 2023, the Company recorded $0.7 million of stock-based compensation included in general and administrative expense in its consolidated statements of operations.

For the years ended December 31, 2024 and 2023, the Company recorded $0.3 and $0.6 million, respectively, of stock-based compensation included in general and administrative expense in its consolidated statements of operations related to Mr. Angermayer's service as Chairman of the Company's supervisory board.

21. Defined Contribution Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their annual compensation. Employees may make contributions by having the Company withhold a percentage of their salary up to the Internal Revenue Service annual limit. The Company recorded $0.5 million and $0.5 million of related compensation expense for the years ended December 31, 2024 and 2023.

22. Corporate Restructurings

2024 Restructuring

In February 2024, the Company restructured its workforce and eliminated approximately 10% of its global workforce in order to more effectively allocate its research and development and other resources supporting the revised business and program priorities and to reduce operational costs.

Restructuring expense related to the workforce reduction incurred during the year ended December 31, 2024, resulted in $2.0 million of restructuring expense, which consisted of $1.6 million of cash expenditures for severance and other employee separation-related costs and $0.4 million of non-cash stock-based compensation expense. Of the restructuring expense, for the year ended December 31, 2024, $0.3 million and $1.7 million were recorded in research and development expenses and general and administrative expenses, respectively, in the consolidated statements of operations.

As of December 31, 2024, all restructuring liabilities had been paid in full and there were no restructuring liabilities included in accrued expenses on the Company's consolidated balance sheets.

2023 Restructuring

In February 2023, the Company restructured its workforce and eliminated approximately 30% of its global workforce in order to more effectively allocate its research and development and other resources supporting the revised business and program priorities and to reduce operational costs.

Restructuring expense related to the workforce reduction incurred during the year ended December 31, 2023, resulted in $3.2 million of restructuring expense, which consisted of $3.0 million of cash expenditures for severance and other employee separation-related costs and $0.2 million of non-cash stock-based compensation expense. Of the restructuring expense, for the year ended December 31, 2023, $1.8 million and $1.4 million were recorded in research and development expenses and general and administrative expenses, respectively, in the consolidated statements of operations.

As of December 31, 2023, all restructuring liabilities had been paid in full and there were no restructuring liabilities included in accrued expenses on the Company's consolidated balance sheets.

A reconciliation of the restructuring charges and related payments for the years ended December 31, 2024 and 2023 is as follows (in thousands):

	December 31, 2024	December 31, 2023
Restructuring costs expensed during the period	$ 2,029	$ 3,206
Non-cash impact of stock-based compensation	(358)	(195)
Cash payments of restructuring liabilities, net	(1,671)	(3,011)
Ending Restructuring liability	$ —	$ —

23. Segment Reporting

The Company's operations are organized into one operating and reportable segment dedicated to the global discovery, research, development, and commercialization of highly effective mental health treatments to transform patient outcomes. The Company's Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and makes key operating decisions and assesses performance on a consolidated basis. The Company's determination that it operates as a single operating segment is consistent with the financial information regularly reviewed by the CODM.

The Company's primary operations are located in the United States, Germany, and Canada. The measure of segment assets is reported on the Company's consolidated balance sheets as total assets. Refer to Note 9 for more information regarding the Company's property and equipment assets by geographic region.

The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates. The Company does recognize revenue through its licenses of intellectual property and manufacturing contracts. Refer to Note 19 for more information.

For the Company's single reportable segment, the CODM uses net loss that is reported on the consolidated statements of operations to allocate resources, predominantly during the annual budget and forecasting process. The CODM also uses non-financial inputs and qualitative information to evaluate the Company's performance, establish compensation, monitor budget versus actual results, and decide the level of investment in the Company's various operating activities and other capital allocation activities.

The Company's reportable segment net loss, including significant segment expenses, for the years ended December 31, 2024 and 2023 consisted of the following (in thousands):

	For the year ended December 31,	
	2024	**2023**
License revenue	$ 308	$ 314
Research ad Development		
VLS-01	10,606	9,055
EMP-01	1,527	2,635
RL-007	10,962	8,394
Discovery (Non-hallucinogenic)	2,649	144
Other programs[(i)]	5,994	12,939
Personnel and employee-related expenses[(ii)]	10,545	14,054
Non-cash share-based compensation expense	10,390	12,361
Depreciation	184	—
Other Expenses[(iii)]	2,597	2,621
General and Administrative		
Personnel and employee-related expenses[(ii)]	12,493	14,888
Non-cash share-based compensation expense	14,767	20,183
Accounting and Tax Fees	5,057	6,790
Legal & Intellectual Property Fees	5,895	8,770
Insurance	2,328	3,692
Depreciation and Amortization	290	307
Other Expenses[(iii)]	6,715	8,952
Interest income	778	1,847
Interest expense	(3,124)	(2,656)
Other segment items[(iv)]	(45,012)	82,385
Segment and consolidated net loss	**$ (150,049)**	**$ (43,895)**

[(i)] Includes direct expenses related to PCN-101, KUR-101, RLS-01, EGX-121, IGX, enabling technologies, and other discovery programs.
[(ii)] Includes labor, benefits, and personnel-based restructuring expenses.
[(iii)] Includes, professional consulting services, facilities costs, technology and communication costs, and miscellaneous fees.
[(iv)] Includes benefit from research and development tax credit, change in fair value of assets and liabilities, net, gain on settlement of pre-existing contract, impairment of other investments, gain on deconsolidation of a variable interest entity, net, gain on dissolution of a variable interest entity, foreign exchange gains (losses), net, benefit (provision) for income taxes, and losses from investments in equity method investees, net of tax.

24. Subsequent Events

Hercules 4th Amendment

In January 2025, the Borrowers and certain Subsidiary Guarantors entered into the Fourth Amendment with the Lenders and Hercules, in its capacity as the Agent, which amended that certain Loan and Security Agreement, dated August 9, 2022 (as amended by the First Amendment, the Second Amendment, the Third Amendment, and the Fourth Amendment the "2022 Term Loan Agreement") to, among other things, consent to the conversion of ATAI AG from a German stock corporation (Aktiengesellschaft – AG) into a German limited liability company (Gesellschaft mit beschränkter Haftung – GmbH).

Proposed Public Offering of Common Shares

In February 2025, the Company issued and sold an aggregate principal amount of $55.0 million of its common shares pursuant to an underwritten public offering. The Company granted the underwriter a 30-day option to purchase up to an additional $8.3 million of common shares. The underwriter elected to purchase $8.3 million of additional common shares pursuant to the option granted by the Company. A related party participated in the public offering, purchasing 10,835,718 common shares for $22.8 million. All common shares sold in the offering were sold by the Company. The Company intends to use the net proceeds from this offering for general corporate purposes, including for working capital and to advance the clinical development of its product candidates and programs.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2024. Based on this evaluation our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2024 at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management, including our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2024, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) or 15d-15(d) of the Exchange Act) identified in management's evaluation during the quarter ended December 31, 2024 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

(b) Insider trading arrangements and policies.

During the three months ended December 31, 2024, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

We have adopted a written code of conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A current copy of the code is posted in the "Investors" section of our website under "Corporate Governance," which is located at https://ir.atai.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our code of conduct, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified in the preceding sentence. The information contained on our website is not incorporated by reference into this Form 10-K. We granted no waivers under our code of conduct in 2024.

Information About Our Directors and Executive Officers

The following table provides information regarding our executive officers and members of our supervisory board of directors (ages as of the date of this Annual Report on Form 10-K):

Name	Age	Position at atai	Principal Employment
Srinivas Rao, Ph.D, M.D.	56	Chief Executive Officer	Same
Anne Johnson	56	Chief Financial Officer	Same
Sahil Kirpekar, M.D.	40	Chief Business Officer	Same
Glenn Short, Ph.D	55	Chief Scientific Officer	Same
Kevin Craig, M.D.	52	Chief Medical Officer	Same
Gerd Kochendoerfer, Ph.D.	57	Chief Operating Officer	Same
Christian Angermayer	46	Founder and Chairman	Founder of Apeiron Investment Group, an investment company
Sabrina Martucci Johnson	58	Supervisory Director	Founder and Chief Executive Officer of Daré Bioscience, Inc., a biopharmaceutical company
Amir Kalali, M.D.	59	Supervisory Director	Professor of Psychiatry at the University of California San Diego
Andrea Heslin Smiley	57	Supervisory Director	President and Chief Executive Officer of VMS BioMarketing, a biomarketing company
Scott Braunstein, M.D.	61	Supervisory Director	Founder, In Situ Healthcare Consulting
Laurent Fischer, M.D.	61	Supervisory Director	Chief Executive Officer and President of Adverum Biotechnologies, a biopharmaceutical company

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report

(a)(1) Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

(a)(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report or the notes thereto or is not applicable or required.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	Open Market Sale Agreement, dated as of November 10, 2022, between ATAI Life Sciences N.V. and Jefferies LLC	8-K	001-40493	1.1	11/10/2022	
3.1	Articles of Association of ATAI Life Sciences N.V. (translated into English), currently in effect	S-3	333-265970	3.1	7/01/2022	
3.2	Rules of the Management Board of ATAI Life Sciences N.V.	S-1/A	333- 255383	3.2	6/11/2021	
3.3	Rules of the Supervisory Board of ATAI Life Sciences N.V.	S-1/A	333- 255383	3.3	6/11/2021	
4.1	Form of Share Issue Deed	S-1/A	333- 255383	3.4	6/11/2021	
4.2	Description of Securities					*
10.1#	Separation Agreement, dated May 14, 2024, by and between the Registrant and Florian Brand	8-K	001-40493	10.1	5/15/2024	
10.2#	Second Amended and Restated Employment Agreement, dated January 8, 2025, between atai Life Sciences US, Inc. and Srinivas Rao	8-K	001-40493	10.1	1/10/2025	
10.3#	Secondment Letter, dated October 17, 2024, by and between atai Life Sciences US Inc. and Srinivas Rao					*
10.4#	Amended and Restated Employment Agreement, dated May 10, 2023, by and between atai Life Sciences US Inc. and Anne Johnson					*
10.5#	Employment Agreement, dated November 11, 2025, by and between Gerd Kochendoerfer and ATAI Life Sciences AG	8-K	001-40493	10.2	1/10/2025	
10.6#	Form of Indemnification Agreement between ATAI Life Sciences N.V. and members of the Supervisory Board or Management	S-1/A	333- 255383	10.4	6/11/2021	
10.7#	Atai Life Sciences N.V. 2021 Incentive Award Plan	S-1/A	333- 255383	10.5	6/11/2021	
10.8#	Form of Option Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.17	6/11/2021	

10.9#	Form of Restricted Stock Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.18	6/11/2021
10.10#	Form of Restricted Stock Unit Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.19	6/11/2021
10.11#	2020 Employee, Director, and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.20	6/11/2021
10.12#	Form of Stock Option Agreement under 2020 Employee, Director and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.21	6/11/2021
10.13#	Remuneration Policy for the Board of Supervisory Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.23	6/11/2021
10.14#	Remuneration policy for the Board of Managing Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.24	6/11/2021
10.15†	License Agreement, dated as of August 14, 2017, between National University Corporation Chiba University and Perception Neurosciences, Inc., as amended by Amendment No. 1, dated as of August 7, 2018, the Second Amendment, dated as of March 17, 2020, and Amendment No. 3, dated as of March 5, 2021.	S-1	333-255383	10.8	4/20/2021
10.16†	Stock Purchase Agreement, dated as of June 8, 2020, between The Trustees of Columbia University in the City of New York and Kures, Inc.	S-1	333-255383	10.9	4/20/2021
10.17†	Preferred Stock Purchase Agreement, dated as of August 29, 2019, between GABA Therapeutics, Inc. and ATAI Life Sciences AG, as amended by the Omnibus Amendment, dated as of October 30, 2020	S-1	333-255383	10.11	4/20/2021
10.18†	Series A Preferred Stock Purchase Agreement, dated as of December 27, 2019, among DemeRx IB, Inc., ATAI Life Sciences AG and DemeRx, Inc.	S-1	333-255383	10.13	4/20/2021
10.19†	Series A Preferred Stock Purchase Agreement, dated as of November 6, 2020, between FSV7, Inc. and ATAI Life Sciences AG	S-1/A	333-255383	10.13	5/27/2021
10.20†	Amended and Restated License Agreement, dated as of February 21, 2020, between Allergan Sales, LLC and FSV7, LLC	S-1	333-255383	10.14	4/20/2021
10.21†	License and Collaboration Agreement, dated as of March 11, 2021, between Perception Neuroscience, Inc. and Otsuka Pharmaceutical Co., Ltd.	S-1/A	333-255383	10.16	5/27/2021
10.22	Partnership Agreement of ATAI Life Sciences HSOP GbR, dated August 21, 2020	S-1/A	333-255383	10.22	6/11/2021

10.23	Amendment to Preferred Stock Purchase Agreement, dated as of May 15, 2021, by and among ATAI Life Sciences AG, GABA Therapeutics, LLC and GABA Therapeutics, Inc.	S-1/A	333-255383	10.26	6/4/2021	
10.24†	Loan and Security Agreement between the Registrant, ATAI Life Sciences AG, certain of the Registrant's subsidiaries from time to time party thereto as a guarantor, Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. as administrative agent and collateral agent for itself and the lenders, dated August 9, 2022	10-Q	001-40493	10.1	8/15/2022	
10.25	First Amendment to Loan and Security Agreement between the Registrant, ATAI Life Sciences AG, certain of the Registrant's subsidiaries from time to time party thereto as a guarantor, Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. as administrative agent and collateral agent for itself and the lenders, dated March 13, 2023	10-K	001-40493	10.27	3/24/2023	
10.26†	Second Amendment to the Loan and Security Agreement between the Registrant, ATAI Life Sciences AG, certain of the Registrant's subsidiaries from time to time party thereto as a guarantor, Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. as administrative agent and collateral agent for itself and the lenders, dated May 26, 2023	8-K	001-40493	10.1	5/31/2023	
10.27†	Third Amendment to the Loan and Security Agreement between the Registrant, ATAI Life Sciences AG, certain of the Registrant's subsidiaries from time to time party thereto as a guarantor, Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. as administrative agent and collateral agent for itself and the lenders, dated August 14, 2024.	8-K	001-40493	10.1	8/14/2024	
10.28†	Consent and Fourth Amendment to the Loan and Security Agreement between the Registrant, ATAI Life Sciences AG, certain of the Registrant's subsidiaries from time to time party thereto as a guarantor, Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party thereto, and Hercules Capital, Inc. as administrative agent and collateral agent for itself and the lenders, dated January 6, 2025.					*
10.29†	Amendment to Series A Preferred Stock Purchase Agreement, dated as of May 25, 2021, by and among ATAI Life Sciences AG and FSV7, Inc.	10-K	001-40493	10.28	3/4/2023	

10.30†	Second Amendment to Series A Preferred Stock Purchase Agreement, dated as of September 17, 2021, by and among ATAI Life Sciences AG and Recognify Life Sciences Inc., f/k/a FSV7, Inc.	10-K	001-40493	10.29	3/4/2023	
10.31†	Omnibus Amendment to Series A Preferred Stock Purchase Agreement, dated as of October 5, 2022, by and among ATAI Life Sciences AG and Recognify Life Sciences, Inc., f/k/a FSV7, Inc.	10-K	001-40493	10.30	3/4/2023	
10.32#	Separation Agreement between Mr. Stephen Bardin and atai Life Sciences N.V., dated February 6, 2024	8-K	001-40493	10.1	2/6/2024	
10.33#†	Termination and New Consultancy Agreement, by and among the Company, ATAI AG and Christian Angermayer, dated January 7, 2024	8-K	001-40493	10.1	1/9/2024	
10.34	Fourth Amendment to Series A Preferred Stock Purchase Agreement by and among atai Life Sciences AG, Recognify Life Sciences, Inc., f/k/a FSV7, Inc., and the Shareholders (as listed on Exhibit A)	10-Q	001-40493	10.2	11/14/2023	
10.35†	Amended and Restated Subscription and Shareholders' Agreement Relating to Beckley Psytech Limited, dated January 3, 2024, by and among the Company, Beckley Psytech Limited, and certain other persons set forth therein	8-K	001-40493	10.1	1/4/2024	
10.36†	Share Purchase Deed, dated January 18, 2024, by and among the Company, Beckley Psytech Limited, and certain other persons set forth therein	8-K	001-40493	10.1	1/23/2024	
10.37†	Fourth Amendment to Series A Preferred Stock Purchase Agreement by and among atai Life Sciences AG, Recognify Life Sciences, Inc., f/k/a FSV7, Inc., and the Shareholders (as listed on Exhibit A)	10-Q	001-40493	10.2	5/15/2024	
19.1	Insider Trading Compliance Policy					*
21.1	List of Subsidiaries					*
23.1	Consent of Deloitte & Touche LLP, an independent registered public accounting firm					*
31.1	Certification of Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a)					*
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a)					*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350					**
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350					**

97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-40493	97.1	3/28/2024	
101.INS	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, Financial Statements and Supplementary Data, of this Form 10-K					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
# Management contract or compensatory plan, contract or arrangement.
† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit pursuant to Regulation S-K, Item 601(b)(10)(iv).

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**.**

ATAI LIFE SCIENCES N.V.

Date: March 17, 2025

By: /s/ Srinivas Rao
Srinivas Rao
Chief Executive Officer

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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Srinivas Rao Srinivas Rao	Chief Executive Officer (Principal Executive Officer)	March 17, 2025
/s/ Anne Johnson Anne Johnson	Chief Financial Officer (Principal Financial Officer)	March 17, 2025
/s/ Christian Angermayer Christian Angermayer	Chairman of the Supervisory Board	March 17, 2025
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Supervisory Director	March 17, 2025
/s/ Amir Kalali Amir Kalali	Supervisory Director	March 17, 2025
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Supervisory Director	March 17, 2025
/s/ Scott Braunstein Scott Braunstein	Supervisory Director	March 17, 2025
/s/ Laurent Fischer Laurent Fischer	Supervisory Director	March 17, 2025

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF
THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

ATAI Life Sciences N.V. (the "Company," "we," "us" and "our") has the following class of securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, par value €0.10 per share	ATAI	The Nasdaq Global Market

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

The following is a summary of relevant information concerning our share capital and our articles of association and applicable Dutch law. This summary does not constitute legal advice regarding those matters and should not be regarded as such. The following summary is not complete and is subject to, and is qualified in its entirety by reference to, the provisions of our articles of association, as amended from time to time, and which have been publicly filed with the U.S. Securities and Exchange Commission ("SEC").

General

We are a Dutch a public company (*naamloze vennootschap*). Our affairs are governed by the provisions of our articles of association and internal rules, regulations and policies, as amended and restated from time to time, and by the provisions of applicable Dutch law. As provided in our articles of association, subject to Dutch law, we have full capacity to carry on or undertake any business or activity, do any act or enter into any transaction consistent with the objects specified in our articles of association, and, for such purposes, full rights, powers and privileges.

Share Capital

As of December 31, 2022, our authorized share capital amounted to €75,000,000, consisting of 750,000,000 shares, each with a nominal value of €0.10.

Common Shares

The following summarizes the main rights of holders of our common shares:

- each holder of common shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the appointment of managing directors and supervisory directors;
- there are no cumulative voting rights;
- the holders of our common shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any;
- upon our liquidation, dissolution or winding-up, the holders of common shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities; and
- the holders of common shares have preemptive rights in case of share issuances or the grant or rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Dutch law and our articles of association.

Amendment of Articles of Association

The articles of association can only be amended by a general meeting of the shareholders proposed by the management board, with the approval of the supervisory board. A resolution of the general meeting of shareholders to amend the articles of association requires a majority of at least two thirds of the votes cast and that majority must represent more than half of the issued capital.

Shareholders' Register

Pursuant to Dutch law and our articles of association, we must keep our shareholders' register accurate and current. Our management board keeps our shareholders' register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of use (*vruchtgebruik*) on registered shares belonging to another or a pledge (*pandrecht*) in respect of such shares. Part of the shareholders register may be kept outside the Netherlands to comply with applicable local law or pursuant to stock exchange rules. Our common shares shall be in registered form (*op naam*).

Corporate Objectives

Pursuant to our articles of association, our main corporate objectives are:

- to build biotech companies globally by leveraging a decentralized, technology- and data-driven platform model to serve millions of people suffering with mental health disorders;
- to acquire and efficiently develop innovative treatments that address significant unmet medical needs and lead to paradigm shifts in the mental health space;
- to, either alone or jointly with others, acquire and dispose of affiliations or other interests in legal entities, companies and enterprises, and to collaborate with and to manage such legal entities, companies or enterprises;
- to acquire, manage, turn to account, encumber and dispose of any property—including intellectual property rights—and to invest capital;
- to supply or procure the supply of money loans, particularly—but not exclusively—to our subsidiaries, group companies and/or affiliates, as well as to draw or to procure the drawing of money loans;
- to enter into agreements whereby we commit ourselves as guarantor or severally liable co-debtor, or grant security or declare ourselves jointly or severally liable with or for others, particularly—but not exclusively—to the benefit of companies as referred to above;
- for purposes not related to the conduct of its business to make periodic payments for or towards pension funds or other objectives; and
- to do all such things as are incidental or may be conducive to the above objects or any of them.

Limitations on the Rights to Own Securities

Our common shares may be issued to individuals, corporations, trusts, estates of deceased individuals, partnerships and unincorporated associations of persons. Our articles of association contain no limitation on the rights to own our shares and no limitation on the rights of nonresidents of the Netherlands or foreign shareholders to hold or exercise voting rights.

Limitation on Liability and Indemnification Matters

Under Dutch law, managing directors, supervisory directors and certain other officers may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to the company and to third parties for infringement of the articles of association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Subject to certain exceptions, our articles of association provide for indemnification of our current and former managing directors and supervisory directors (and other current and former officers and employees as designated by our management board). No indemnification shall be given under our articles of association to an indemnified person:

(a) if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal

proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);

(b) to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);

(c) in relation to proceedings brought by such indemnified person against the company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and the company which has been approved by the management board or pursuant to insurance taken out by the company for the benefit of such indemnified person; and

(d) for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the company's prior consent.

Under our articles of association, our management board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

Federal Forum Provision

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the U.S. Securities Act of 1933, as amended, to the fullest extent permitted by applicable law, shall be the U.S. federal district courts.

Shareholders' Meetings

General meetings of shareholders must be held in Amsterdam, or in Rotterdam, the Hague, at Schiphol Airport in the municipality of Haarlemmermeer, all in the Netherlands. The annual general meeting of shareholders must be held within six months of the end of each financial year. Additional extraordinary general meetings of shareholders may also be held, whenever considered appropriate by the management board or the supervisory board and shall be held within three months after our management board has considered it to be likely that our equity has decreased to an amount equal to or lower than half of its paid up and called up share capital, in order to discuss the measures to be taken if so required.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party/parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting of shareholders. The court shall disallow the application if it does not appear that the applicants have previously requested our management board and our supervisory board to convene a general meeting and neither our management board nor our supervisory board has taken the necessary steps so that the general meeting could be held within six weeks after the request. The application shall also be disallowed if the proponent(s) has/have not demonstrated to have a reasonable interest in the convening of the general meeting

General meetings of shareholders must be convened by an announcement published in a Dutch daily newspaper with national distribution, which shall include an agenda, the time and place of the meeting, the record date (if any), the procedure for participating in the general meeting by proxy, as well as other information as required by Dutch law. The notice must be given at least 15 calendar days prior to the day of the meeting. The agenda for the annual general meeting of shareholders shall include, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of the management board and supervisory board, including the filling of any vacancies. In addition, the agenda shall include such items as have been included therein by the management board or the supervisory board. The agenda shall also include such items requested by one or more shareholders, or others with meeting rights under Dutch law, representing at least 3% of the issued share capital. These requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

In accordance with the DCGC, shareholders who have the right to put an item on the agenda for our general meeting or to request the convening of a general meeting shall not exercise such rights until after they have consulted our management board. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more of our managing directors or supervisory directors), our management board must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our management board must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time,

our management board, supervised by our supervisory board, shall report on this consultation and the exploration of alternatives to our general meeting. The response period may be invoked only once for any given general meeting and shall not apply (i) in respect of a matter for which either a response period or a statutory cooling-off period (as discussed below) has been previously invoked or (ii) in situations where a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

Moreover, our management board, with the approval of our supervisory board, can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting or their right to request a general meeting, propose an agenda item for our general meeting to dismiss, suspend or appoint one or more managing directors or supervisory directors (or to amend any provision in our articles of association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our management board believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting cannot dismiss, suspend or appoint managing directors and supervisory directors (or amend the provisions in our articles of association dealing with those matters) except at the proposal of our management board. During a cooling-off period, our management board must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, our management board must publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- our management board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of our company and its business;
- our management board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

The general meeting is presided over by the chairperson of the supervisory board or by the CEO or by the person designated thereto by the supervisory board, whether or not from its midst. If the chairperson and the CEO are absent and the supervisory board has not designated another person as aforesaid, the general meeting itself shall appoint its chairperson. Managing directors and supervisory directors may always attend a general meeting of shareholders. In these meetings, they have an advisory vote. The chairperson of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting of shareholders, to address the meeting and, in so far as they have such right, to vote pro rata to his or her shareholding. Shareholders may exercise these rights, if they are the holders of shares on the record date, if any, as required by Dutch law, which is currently the 28th day before the day of the general meeting of shareholders. Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting of shareholders. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Each common share confers the right on the holder to cast one vote at the general meeting of shareholders. Shareholders may vote by proxy. No votes may be cast at a general meeting of shareholders on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depositary receipts. Nonetheless, the holders of a right of use (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting of shareholders.

Decisions of the general meeting of shareholders are taken by an absolute majority of votes cast, except where Dutch law or our articles of association provide for a qualified majority or unanimity. Subject to any provision of mandatory Dutch law and any higher

quorum requirement stipulated by our articles of association, if we would be subject to the requirement that our general meeting can only pass resolutions if a certain part of our issued share capital is present or represented at such general meeting under applicable securities laws or listing rules, then such resolutions shall be subject to a quorum of one third of our issued and outstanding shares being present or represented at our general meeting.

Managing Directors and Supervisory Directors

Appointment of Managing Directors and Supervisory Directors

Under our articles of association, the managing directors and supervisory directors are appointed by the general meeting of shareholders upon binding nomination by our supervisory board. Our articles of association provide that only managing directors that are resident in Germany may be appointed as CEO and that at least half of the managing directors should be German resident. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of shareholders overrules the binding nomination, the supervisory board shall make a new nomination. If the nomination is comprised of one candidate for a vacancy, a resolution concerning the nomination shall result in the appointment of the candidate, unless the nomination is overruled.

Our supervisory board has adopted a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

At a general meeting of shareholders, a resolution to appoint a managing director or supervisory director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting of shareholders or in the explanatory notes thereto.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

Duties and Liabilities of Managing Directors and Supervisory Directors

Under Dutch law, the management board is charged with the management of the company, which includes setting the company's policies and strategy, subject to the restrictions contained in our articles of association, and the supervisory board is charged with the supervision of the policy of the management board and the general course of affairs of the company and of the business connected with it. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of the management board regarding a material change in our identity or character requires approval of the general meeting of shareholders.

Our board is entitled to represent our company. The power to represent our company also vests in the CEO individually, as well as in any other two managing directors acting jointly.

Dividends and Other Distributions

Dividends

Under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed.

Under our articles of association, the management board, with the approval of our supervisory board, may decide that all or part of the profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation by the management board of any profit, any remaining profits will be at the disposal of the general meeting of shareholders at the proposal of our managing board for distribution, subject to restrictions of Dutch law and approval by our supervisory board.

The management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting of shareholders, but only with the approval of the supervisory board.

Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

We have not adopted a dividend policy with respect to future dividends. Subject the restrictions described above, any dividend policy (if we were to adopt one) will depend on many factors, such as our results of operations, financial condition, cash requirements, prospects and other factors deemed relevant by our management board and supervisory board.

We do not anticipate paying any cash dividends for the foreseeable future.

Exchange Controls

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to EU regulations, the Sanctions Act 1977 (*Sanctiewet* 1977) or other legislation, applicable anti-boycott regulations, applicable anti-money-laundering regulations and similar rules and provided that, under certain circumstances, payments of such dividends or other distributions must be reported to the Dutch Central Bank at their request for statistical purposes. There are no special restrictions in our articles of association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

Squeeze-Out Procedures

Pursuant to Section 2:92a of the Dutch Civil Code, a shareholder who holds at least 95% of our issued share capital for his own account, alone or together with group companies, may initiate proceedings against the other shareholders jointly for the transfer of their shares to such shareholder. The proceedings are held before the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber, (*Ondernemingskamer*), and can be instituted by means of a writ of summons served upon each of the other shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to the other shareholders and will determine the price to be paid for the shares, if necessary, after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the other shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

Dissolution and Liquidation

Under our articles of association, we may be dissolved by a resolution of the general meeting of shareholders, subject to a proposal of the management board approved by our supervisory board. In the event of a dissolution, the liquidation shall be effected by the management board, under supervision of our supervisory board, unless the general meeting decides otherwise. During liquidation, the provisions of our articles of association will remain in force as far as possible. To the extent that any assets remain after payment of all of our liabilities, any remaining assets shall be distributed to our shareholders in proportion to their number of shares.

Dutch Corporate Governance Code

As a listed Dutch public company (*naamloze vennootschap*), we will be subject to the DCGC. The DCGC contains both principles and best practice provisions on corporate governance that regulate relations between the management board, the supervisory board and the general meeting of shareholders and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a “comply or explain” principle. Accordingly, companies are required to disclose in their statutory annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If a company subject to the DCGC does not comply with these provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such non-compliance.

We will not comply with all principles and best practice provisions of the DCGC, including in order to follow market practice or governance practices in the United States.

Dutch Financial Reporting Supervision Act

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), or the FRSA, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*), or the AFM, supervises the application of financial reporting standards by Dutch companies whose securities are listed on a Dutch or foreign stock exchange.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt that our financial reporting meets such standards and (ii) recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer*) order us to (a) make available further explanations as recommended by the AFM, (b) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (c) prepare or restate our financial reports in accordance with the Enterprise Chamber's orders.

Foreign Investment Legislation

Under existing laws of the Netherlands, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to EU regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations, anti-money laundering regulations and similar rules.

Transfer Agent and Registrar

The transfer agent and registrar for the common shares will be Computershare Trust Company, N.A.

Comparison of Dutch Corporate Law and U.S. Corporate Law

The following is a comparison between Dutch corporate law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated. Although we believe this summary is materially accurate, the summary is subject to Dutch law, including Book 2 of the Dutch Civil Code and the DCGC and Delaware corporation law, including the Delaware General Corporation Law, or DGCL.

Corporate Governance

Duties of Managing Directors and Supervisory Directors

The Netherlands. In the Netherlands, a listed company typically has a two-tier board structure with a management board (*bestuur*) comprised of the managing directors (executive directors) and a supervisory board (*raad van commissarissen*) comprised of the supervisory directors (non-executive directors). We have a two-tier board structure consisting of our management board and a separate supervisory board.

Under Dutch law, the management board is charged with the management of the company, which includes setting the company's policies and strategy, subject to the restrictions contained in our articles of association, and the supervisory board is charged with the supervision of the policy of the management board and the general course of affairs of the company and of the business connected with it. Our managing directors and supervisory directors may divide their tasks among themselves in or pursuant to internal rules. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of the management board regarding a material change in our identity or character requires approval of the general meeting.

The approval of our supervisory board is required for certain resolutions of our management board, including concerning the following matters: the making of certain proposals to the general meeting (including the issue of shares or the granting of rights to subscribe for shares; the limitation or exclusion of pre-emption rights; the designation or granting of certain authorizations as referred to in our articles of association, the reduction of our issued share capital; the making of a distribution from the Company's profits or reserves; the determination that all or part of a distribution, instead of being made in cash, shall be made in the form of shares or in the form of assets; the amendment of our articles of association; the entering into of a merger or demerger; the instruction of the management board to apply for the Company's bankruptcy and our dissolution); the issue of shares or the granting of rights to subscribe for shares; the limitation or exclusion of pre-emption rights; the acquisition of shares by us in our own capital; the drawing up or amendment of our management board rules; the performance of legal acts relating to non-cash contributions on shares; material changes to the identity or the character of the company or its business; the charging of amounts to be paid up on shares against the company's reserves; the making of an interim distribution the amendment of the articles of association, the entering into of a merger

or demerger, the instruction to apply for the Company's bankruptcy, the Company's dissolution; and such other resolutions as the supervisory board shall have specified in a resolution to that effect and notified to the management board. The absence of the approval of the supervisory board shall result in the relevant resolution being null and void but shall not affect the powers of representation of the management board or of the managing directors.

Our management board is entitled to represent us. The power to represent us also vests in the chief executive officer individually, as well as in any other two managing directors acting jointly.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.

Director Terms

The Netherlands. The DCGC provides the following best practice recommendations on the terms for tenure of our managing directors and supervisory directors:

- Managing directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms managing directors may serve.

- Supervisory directors should be appointed for two consecutive periods of no more than four years. Thereafter, supervisory directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that the reasons for any reappointment after an eight-year term of office should be disclosed in the company's annual report.

The general meeting shall at all times be entitled to suspend or dismiss a managing director or supervisory director. Under our articles of association, the general meeting may only adopt a resolution to suspend or dismiss such director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the resolution is passed at the proposal of the supervisory board, in which latter case a simple majority of the votes cast is sufficient. In addition, the supervisory board may at any time suspend a managing director. A suspension by the supervisory board can at any time be lifted by the general meeting. If a managing director or supervisory director is suspended and the general meeting does not resolve to dismiss him or her within three months from the date of such suspension, the suspension shall lapse.

Delaware. The DGCL generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the shareholders. A director elected to serve a term on a "classified" board may not be removed by shareholders without cause. There is no limit in the number of terms a director may serve.

Vacancies

The Netherlands. Our management board and supervisory board can temporarily fill vacancies in its midst caused by temporary absence or incapacity of managing directors or supervisory directors, respectively, without requiring a shareholder vote. If all of our managing directors are absent or incapacitated, our management shall be attributed to a person designated by the supervisory board (or, in the absence of such designation, a person designated by our general meeting). If all of our supervisory directors are absent or incapacitated, our supervision shall be attributed to the person who most recently ceased to hold office as the chairperson of our supervisory board. The person(s) charged with our supervision in this manner may designate one or more persons to be charged with our supervision instead of, or together with, such person(s).

Under Dutch law, our managing directors and supervisory directors are appointed and reappointed by the general meeting. Under our articles of association, managing directors and supervisory directors are appointed by the general meeting upon the binding nomination by our supervisory board. However, the general meeting may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital. If the general meeting overrules the binding nomination, the supervisory board shall make a new nomination.

Our supervisory board has adopted a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a

managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director; and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

Delaware. The DGCL provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-Interest Transactions

The Netherlands. Under Dutch law and our articles of association, our managing directors and supervisory directors shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a direct or indirect personal conflict of interest with us. Such a conflict of interest would generally arise if the managing director or supervisory director concerned is unable to serve our interests and business connected with it with the required level of integrity and objectivity due to the existence of the conflicting personal interest. Our articles of association provide that a managing director shall not participate in the deliberations and decision-making of the management board on a matter in relation to which he has a direct or indirect personal interest that conflicts with our interests and of the business connected with it. If, as a result thereof, no resolution can be passed by the management board, the resolution shall be passed by the supervisory board. Our articles of association further provide that a supervisory director shall not participate in the deliberations and decision-making of the supervisory board on a matter in relation to which he has a direct or indirect personal interest that conflicts with our interests and of business connected with it. If, as a result thereof, no resolution can be passed by the supervisory board, the resolution may nevertheless be passed by the supervisory board as if none of the supervisory directors has such conflict of interests.

The DCGC provides the following best practice recommendations in relation to conflicts of interests in respect of managing directors or supervisory directors:

- A managing director should report any potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairperson of the supervisory board and to the other members of the management board without delay. The managing director should provide all relevant information in that regard, including the information relevant to the situation concerning his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree.

- A supervisory director should report any conflict of interest or potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairman of the supervisory board without delay and should provide all relevant information in that regard, including the relevant information pertaining to his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree. If the chairman of the supervisory board has a conflict of interest or potential conflict of interest, he or she should report this to the vice-chairman of the supervisory board without delay.

- The supervisory board should decide, outside the presence of the managing director or supervisory director concerned, whether there is a conflict of interest.

- All transactions in which there are conflicts of interest with managing directors or supervisory directors should be agreed on terms that are customary in the market.

- Decisions to enter into transactions in which there are conflicts of interest with managing directors or supervisory directors that are of material significance to the company and/or to the relevant managing directors or supervisory directors should require the approval of the supervisory board. Such transactions should be published in the annual report, together with a description of the conflict of interest and a declaration that the relevant best practice provisions of the DCGC have been complied with.

Delaware. The DGCL generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;

- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the shareholders.

Proxy Voting by Directors

The Netherlands. An absent managing director may issue a proxy for a specific management board meeting but only to another managing director in writing or by electronic means. An absent supervisory director may issue a proxy for a specific supervisory board meeting but only to another supervisory director in writing or by electronic means.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder Rights

Voting Rights

The Netherlands. In accordance with Dutch law and our articles of association, each issued common share confers the right to cast one vote at the general meeting. Each holder of shares may cast as many votes as it holds shares. No votes may be cast on shares that are held by us or our direct or indirect subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting of shareholders.

Subject to any provision of mandatory Dutch law and any higher quorum requirement stipulated in our articles of association, if and for as long as the Company is subject to the rules and requirements of a securities exchange and such securities exchange requires the Company to have a quorum for the general meeting of shareholders, then the general meeting of shareholders can only pass resolutions if at least one third of our issued and outstanding shares are present or represented at such general meeting.

In accordance with our articles of association, for each general meeting, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting which must be published in a Dutch daily newspaper with national distribution at least 15 calendar days prior to the meeting (and such notice may therefore be published after the record date for such meeting). Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Delaware. Under the DGCL, each shareholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Shareholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the shareholders of record entitled to notice or to vote at a meeting of shareholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

The Netherlands. Pursuant to our articles of association, extraordinary general meetings will be held whenever required under Dutch law or whenever our management board or supervisory board deems such to be appropriate or necessary. Pursuant to Dutch law, one

or more shareholders or others with meeting rights under Dutch law jointly representing at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party or parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting. The court shall disallow the application of it does not appear that the requesting party or parties has/have previously requested our management board and supervisory board to convene a general meeting of shareholders and neither our management board nor our supervisory board has taken the necessary steps so that the general meeting could be held within six weeks after the request. The application shall also be disallowed if the proponent(s) has/have not demonstrated to have a reasonable interest in the convening of the general meeting.

The agenda for our general meetings shall also include such items requested by one or more shareholders, and others with meeting rights under Dutch law, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our articles of association do not state such lower percentage. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting.

In accordance with the DCGC, shareholders who have the right to put an item on the agenda for our general meeting or to request the convening of a general meeting shall not exercise such rights until after they have consulted our management board. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more of our managing directors or supervisory directors), our management board must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our management board must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time, our management board, supervised by our supervisory board, shall report on this consultation and the exploration of alternatives to our general meeting. The response period may be invoked only once for any given general meeting and shall not apply (i) in respect of a matter for which either a response period or a statutory cooling-off period (as discussed below) has been previously invoked or (ii) in situations where a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

Moreover, our management board, with the approval of our supervisory board, can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting or their right to request a general meeting, propose an agenda item for our general meeting to dismiss, suspend or appoint one or more managing directors or supervisory directors (or to amend any provision in our articles of association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our management board believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting cannot dismiss, suspend or appoint managing directors and supervisory directors (or amend the provisions in our articles of association dealing with those matters) except at the proposal of our management board. During a cooling-off period, our management board must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, our management board must publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- our management board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of our company and its business;
- our management board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

Delaware. Delaware law does not specifically grant shareholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a shareholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

The Netherlands. Under Dutch law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent, (ii) the company has not issued bearer shares or, with its cooperation, depository receipts for shares in its capital, and (iii) the resolution is adopted unanimously by all shareholders that are entitled to vote. Although our articles of association allow for shareholders' resolutions to be adopted in writing, the requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for us as a publicly traded company.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit shareholders of a corporation to take action by written consent.

Appraisal Rights

The Netherlands. Subject to certain exceptions, Dutch law does not recognize the concept of appraisal or dissenters' rights. However, Dutch law does provide for squeeze-out procedures as described under "Dividends and Other Distributions — Squeeze-Out Procedures." Also, Dutch law provides for cash exit rights in certain situations for dissenting shareholders of a company organized under Dutch law entering into certain types of mergers. In those situations, a dissenting shareholder may file a claim with the Dutch company for compensation. Such compensation shall then be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the merger.

Delaware. The DGCL provides for shareholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the shareholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

The Netherlands. In the event a third-party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third-party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third-party in its own name. Dutch law provides for the possibility to initiate such actions collectively, in which a foundation or an association can act as a class representative and has standing to commence proceedings and claim damages if certain criteria are met. The court will first determine if those criteria are met. If so, the case will go forward as a class action on the merits after a period allowing class members to opt out from the case has lapsed. All members of the class who are residents of the Netherlands and who did not opt-out will be bound to the outcome of the case. Residents of other countries must actively opt in in order to be able to benefit from the class action. The defendant is not required to file defenses on the merits prior to the merits phase having commenced. It is possible for the parties to reach a settlement during the merits phase. Such a settlement can be approved by the court, which approval will then bind the members of the class, subject to a second opt-out. This new regime applies to claims brought after January 1, 2020 and which relate to certain events that occurred prior to that date. For other matters, the old Dutch class actions regime will apply. Under the old regime, no monetary damages can be sought. Also, a judgment rendered under the old regime will not bind individual class members. Even though Dutch law does not provide for derivative suits, managing directors and supervisory directors and officers can still be subject to liability under U.S. securities laws.

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the U.S. Securities Act of 1933, as amended, to the fullest extent permitted by applicable law, shall be the U.S. federal district courts.

Delaware. Under the DGCL, a shareholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated shareholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a shareholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a shareholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

The Netherlands. Under Dutch law, when issuing shares, a public company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company such as ours may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-in and called-up share capital plus any reserves required by Dutch law or its articles of association and (ii) the aggregate nominal value of shares of the company which the company acquires, holds or on which the company holds a pledge

(*pandrecht*) or which are held by a subsidiary of the company, would not exceed 50% of its then-current issued share capital. Such company may only acquire its own shares if its general meeting has granted the management board the authority to effect such acquisitions.

An acquisition of common shares for a consideration must be authorized by our general meeting. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. The actual acquisition may only be effected pursuant to a resolution of our management board, with the approval of our supervisory board.

No authorization of the general meeting is required if fully paid common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee share purchase plan.

Delaware. Under the DGCL, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-Takeover Provisions

The Netherlands. Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, certain provisions of our articles of association may make it more difficult for a third-party to acquire control of us or effect a change in the composition of our management board and supervisory board. These provisions include:

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital;

- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient);

- a provision allowing, among other matters, the former chairman of our supervisory board to manage our affairs if all of our supervisory directors are removed from office or otherwise incapacitated or prevented from acting and to appoint others to be charged with the supervision of our affairs, until new supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above; and

- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board.

In addition, Dutch law allows for staggered multi-year terms of our managing directors and supervisory directors, as a result of which only part of our managing directors and supervisory directors may be subject to appointment or re-appointment in any given year.

Furthermore, in accordance with the DCGC and Dutch law, we may invoke a response period or a cooling-off period in certain instances, as discussed above.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the DGCL also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the DGCL Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested shareholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested shareholder, unless:

- the transaction that will cause the person to become an interested shareholder is approved by the board of directors of the target prior to the transactions;

- after the completion of the transaction in which the person becomes an interested shareholder, the interested shareholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested shareholders and shares owned by specified employee benefit plans; or

- after the person becomes an interested shareholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested shareholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

The Netherlands. The management board and the supervisory board provide the general meeting, within a reasonable amount of time, all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of our company. If the management board or supervisory board invokes such an overriding interest, it must give reasons.

Delaware. Under the DGCL, any shareholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Dismissal of Directors

The Netherlands. Under our articles of association, our managing directors and supervisory directors can only be dismissed by the general meeting by simple majority, provided that our supervisory board proposes the dismissal. In other cases, the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. The DCGC recommends that the general meeting can pass a resolution to dismiss a managing director or supervisory director by simple majority, representing no more than one-third of the issued share capital.

Delaware. Under the DGCL, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, shareholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he or she is a part.

Issuance of Shares

The Netherlands. Under Dutch law, a company's general meeting is the corporate body authorized to resolve on the issuance of shares and the granting of rights to subscribe for shares. The general meeting can delegate such authority to another corporate body of the company, such as the management board, for a period not exceeding five years; this authorization may only be extended from time to time for a maximum period of five years. We may not subscribe for our own shares on issue.

Delaware. All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

Preemptive Rights

The Netherlands. Under Dutch law, in the event of an issuance of common shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to employees or common shares issued against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for shares). Under our articles of association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting. Another corporate body, such as the management board, may restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting to restrict or exclude the preemptive rights or to designate another corporate body as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting..

Delaware. Under the DGCL, shareholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

The Netherlands. Under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of our management board, with

the approval of our supervisory board, and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors we deem relevant.

Under our articles of association, our management board, with the approval of our supervisory board, may decide that all or part of the profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation of any such profits, any remaining profits will be at the disposal of the general meeting for distribution, subject to restrictions of Dutch law and approval by our supervisory board. Our management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting, but only with the approval of the supervisory board. Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Delaware. Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

Shareholder Vote on Certain Reorganizations

The Netherlands. Under Dutch law, the general meeting must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one-third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

Delaware. Under the DGCL, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The DGCL permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the DGCL, no vote of the shareholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, shareholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the shareholders will be entitled to appraisal rights.

Remuneration of Managing Directors and Supervisory Directors

The Netherlands. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our managing directors and supervisory directors, provided that such compensation is consistent with our compensation policy. Changes to such compensation policy will require a vote of our general meeting by simple majority of the votes cast. The supervisory board determines the remuneration of individual managing directors with due observance of the compensation policy at the recommendation of our compensation committee. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting by simple majority of votes cast. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the managing directors and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting.

Delaware. Under the DGCL, the shareholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of the compensation policy may be subject to shareholder vote due to the provisions of U.S. federal securities and tax law.

Exhibit 10.3

SECONDMENT LETTER **ENTSENDEBESTÄTIGUNG**

of / der

atai Life Sciences US Inc.
c/o Industrious NYC
250 West 34th St
New York, NY 10119

(hereinafter "**Home Company**") (nachfolgend "**Heimatgesellschaft**")

to / an

Srinivas Rao
1477 Paseo de las Flores
Encinitas, CA 92024

(hereinafter "**You**") (nachfolgend "**Sie**")

October 17, 2024 / New York

We are pleased to confirm your long-term international secondment to Berlin, Germany (hereinafter" **Host Country**") in your role as managing director of the atai Life Sciences N.V. in Berlin, which is expected to start on January 1st, 2025, subject to the issuance of the relevant residence and work permit.

Wir freuen uns, Ihnen Ihre längerfristige internationale Entsendung nach Berlin, Deutschland (nachfolgend „**Gastland**") in Ihrer Funktion als geschäftsführender Vorstand der atai Life Sciences N.V. in Berlin zu bestätigen, die voraussichtlich am 1. Januar 2025 beginnt, vorbehaltlich der Erteilung der entsprechenden Aufenthalts- und Arbeitsgenehmigung.

We are sure that you will fulfil this role exceptionally well due to your many years of experience and knowledge of our companies.

Wir sind sicher, dass Sie diese Rolle aufgrund Ihrer langjährigen Erfahrungen und Kenntnisse unserer Unternehmen hervorragend ausfüllen werden.

Your Host Company in Germany is

Die Gastgebende Gesellschaft in Deutschland ist die

atai Life Sciences N.V.
Wallstraße 16
10179 Berlin

(hereinafter "**Host Company**")

(nachfolgend "**Gastgebende Gesellschaft**")

Your contact person at the Host Company is

Ihre Kontaktperson bei der Gastgebenden Gesellschaft ist

Claire McNamara
Wallstraße 16
10179 Berlin
Email: claire@atai.life

The following provisions supplement the existing employment agreement and any amendments (hereinafter collectively, the "**Employment Agreement**") as well as any other employment regulations between you and the Home Company. Their validity is limited to the duration of the secondment.

Die nachfolgenden Bestimmungen stellen eine Ergänzung zu dem bestehenden Arbeitsvertrag sowie allen Änderungsvereinbarungen (nachfolgend gemeinsam „**Arbeitsvertrag**") sowie den sonstigen arbeitsvertraglichen Regelungen zwischen Ihnen und der Heimatgesellschaft dar und gelten befristet für die Dauer des Aufenthalts in Deutschland.

Sec. 1
Duration and employment / Condition precedent / Fix-Term

(1) You shall be seconded to the Host Company in Germany with effect from January 1st, 2025.

(2) The secondment is limited until December 31st, 2027 and shall terminate on this date without requiring further declarations unless one Party makes use of its right to premature removal (Sec. 6).

(3) After the assignment is completed, you will return to the Home Company in the USA.

(4) The secondment is subject to the condition that you meet the immigration and other administrative requirements for employment at the place of secondment, in particular that you hold a residence permit and a work permit, which the Home Company will support you to obtain.

§ 1
Entsendungsdauer und Einsatz / aufschiebende Bedingung / Befristung

(1) Sie werden mit Wirkung ab dem 1. Januar 2025 zur Gastgebende Gesellschaft nach Deutschland entsandt.

(2) Die Entsendung ist bis zum 31. Dezember 2027 befristet und endet zu diesem Zeitpunkt, ohne dass es einer weiteren Erklärung bedarf, wenn nicht von dem Recht auf vorzeitige Abberufung (§ 6) Gebrauch gemacht wird.

(3) Nach dem Ende der Entsendung kehren Sie zu der Heimatgesellschaft in die USA zurück.

(4) Die Entsendung steht unter der Bedingung, dass Sie die einwanderungsrechtlichen und anderen verwaltungsrechtlichen Voraussetzungen für eine Arbeitsaufnahme am Einsatzort erfüllen, insbesondere einen Aufenthaltstitel und eine Arbeitserlaubnis besitzen, bei deren Erlangung die Heimatgesellschaft Sie unterstützt.

Sec. 2
Working conditions

(1) The employment relationship with the Home Company shall continue to legally exist during the period of the secondment and shall remain in force.

(2) The working conditions applicable for the Host Company shall apply for the duration of the secondment. This applies in particular with respect to the working hours (currently max. hours 40 per week).

(3) The distribution of the working time depends on the respective business requirements of the Host Company. The beginning and end of working hours shall depend on the respective operational requirements and regulations at the place of secondment.

(4) You shall carry out your duties in the role as “managing director of the atai Life Sciences N.V.“ attached to this Secondment Letter as **Annex 1**, which is an integral part of this Secondment Letter.

(5) You shall be obliged to work overtime as well as weekends within the applicable law at the Host Country at the request of the Host Company. This also applies to work on Sundays and public holidays to the extent legally permissible. The public holidays of the Host County at the registered seat of the Host Company shall apply during the secondment.

§ 2
Arbeitsbedingungen

(1) Das Anstellungsverhältnis mit der Heimatgesellschaft besteht rechtlich während der Zeit der Entsendung fort und bleibt in Vollzug gesetzt.

(2) Für die Dauer der Entsendung gelten die bei der Gastgebenden Gesellschaft in Deutschland zur Anwendung kommenden Beschäftigungsbedingungen. Dies gilt insbesondere bzgl. der Arbeitszeit (zurzeit max. 40 Stunden pro Woche basierend auf einer 5-Tage-Woche).

(3) Die Verteilung der Arbeitszeit richtet sich nach den jeweiligen betrieblichen Bedürfnissen der Gastgebenden Gesellschaft. Beginn und Ende der Arbeitszeit richten sich nach den jeweiligen betrieblichen Erfordernissen und jeweiligen Regelungen bei der Gastgebenden Gesellschaft.

(4) Ihre Tätigkeit umfasst Aufgaben in der Funktion eines „geschäftsführenden Vorstands der atai Life Sciences N.V.“ gemäß der als **Anlage 1** beigefügten Tätigkeitsbeschreibung, die integraler Bestandteil dieser Entsendebestätigung ist.

(5) Sie sind verpflichtet, bei Bedarf bei der Gastgebenden Gesellschaft gegebenenfalls auch Mehr- und Überstunden- sowie Wochenendarbeit im Rahmen der im Gastland geltenden Bestimmungen zu leisten. Dies gilt auch für Arbeit an Sonn- und Feiertagen, soweit dies gesetzlich zulässig ist. Es gelten während der Entsendung die gesetzlichen Feiertage am Sitz der Gastgebenden Gesellschaft im Gastland.

Sec. 3
Remuneration

§ 3
Gehalt

During the secondment, you shall receive your contractual gross annual salary, currently USD572,000 as set forth in your Employment Agreement and supplemented by the Salary Increase Letter from the Home Company dated March 13, 2024. Based on the current exchange rate of USD 1 = EUR 0,91, this equals EUR 523,059.68. The Parties agree that the applicable exchange rate may be subject to fluctuation during the secondment. Therefore, the parties agree that any amounts converted to EUR during the term of the secondment will be based on the exchange rate on the day of payment.

Für die Dauer der Entsendung erhalten sie weiterhin ihr arbeitsvertragliches Brutto-Jahresgehalt iHv 572.000,00 USD (in Worten: fünfhundertsiebenundzwanzigtausend USD). Auf Grundlage des derzeitigen Wechselkurses USD 1 = EUR 0,91 entspricht dies EUR 523.059,68. Die Parteien sind sich einig, dass der Wechselkurs während der Entsendung Schwankungen unterliegen kann. Es wird daher vereinbart, dass sich der Auszahlungsbetrag in Euro nach dem aktuellen Tageswechselkurs des jeweiligen Auszahlungstages richtet.

Sec. 4
Social insurance / note regarding obligation / Premium Subsidy Health insurance

(1) With regard to social insurance, it is intended that you remain in the social insurance scheme of the United States of America as far as possible. If, contrary to all expectations, it is not possible to remain in the social insurance scheme of the United States of America, the legal provisions of the host country shall apply.

(2) The Home Company and the Host Company will attempt to obtain a D/USA 101 certificate based on the Social Security Agreement between Germany and the United States of America dated January 7th, 1976 in the version dated March 6th, 1995.

(3) Please note that only the relevant social security carrier may provide binding information regarding the impact of this Letter in terms of social insurance law.

§ 4
Sozialversicherung / Hinweis Verbindlichkeit / Beitragszuschuss Krankenversicherung

(1) Hinsichtlich der Sozialversicherung ist Ihr Verbleib in der Sozialversicherung der Vereinigten Staaten von Amerika so weit wie möglich beabsichtigt. Sollte wider Erwarten der Verbleib in der Sozialversicherung der Vereinigten Staaten von Amerika nicht möglich sein, gelten die rechtlichen Bestimmungen des Gastlandes.

(2) Die Heimatgesellschaft und die Gastgebende Gesellschaft bemühen sich um die Ausstellung einer D/USA 101 Bescheinigung auf Grundlage des Sozialversicherungsabkommens zwischen Deutschland und den Vereinigten Staaten von Amerika vom 7. Januar 1976 in der Fassung vom 6. März 1995.

(3) Sie wurde darauf hingewiesen, dass verbindliche Auskunft über sozialrechtliche Auswirkungen dieser Bestätigung nur der zuständige Sozialversicherungsträger erteilen kann.

Sec. 5

§ 5

Consideration of employment periods spent abroad

If your length of service is relevant to claim or calculate benefits provided by the Home Company (occupational pension scheme, bonuses etc.), your secondment periods shall be treated as if you had performed your duties in the USA.

Berücksichtigung von im Ausland verbrachten Beschäftigungszeiten

Sofern es für die Inanspruchnahme oder die Berechnung arbeitgeberseitiger Leistungen (betriebliche Altersversorgung, Boni usw.) auf die Betriebszugehörigkeit zur Heimatgesellschaft ankommt, werden Sie hinsichtlich der Zeiten der Entsendung so gestellt, als hätten Sie Ihre Arbeitsleistung in den USA erbracht.

Sec. 6
Premature termination and removal

(1) The Home Company is entitled to prematurely remove you observing a notice period of four weeks and thus terminate the secondment when your conduct, reasons related to your character or urgent operational reasons require the Home Company to act in its interest.

(2) An early termination right shall exist in particular if

- the purpose for the stay abroad is no longer justified,
- the job performed by You posted abroad is finished
- or Your safety is at risk and/or if the responsible Office in the USA has issued travel and safety warnings.

(3) Any necessary costs incurred shall be borne by the Company. The Company shall organize the travel in coordination with you.

§ 6
Vorzeitige Beendigung und Abberufung

(1) Die Heimatgesellschaft ist berechtigt, Sie mit einer Ankündigungsfrist von vier Wochen vorzeitig abzuberufen und damit die Entsendung zu beenden, wenn dies aus Gründen in Ihrer Person oder in Ihrem Verhalten oder aus betrieblichen Gründen im Interesse der Heimatgesellschaft erforderlich ist.

(2) Ein Recht zur vorzeitigen Beendigung besteht insbesondere, wenn

- der Zweck des Auslandsaufenthalts entfallen ist,
- die Tätigkeit, anlässlich derer Sie im Ausland eingesetzt wird, beendet wurde
- oder Ihre Sicherheit gefährdet ist bzw. entsprechende Reise- und Sicherheitswarnungen des zuständigen Amtes in den USA bestehen.

(3) Die hierdurch anfallenden und erforderlichen Kosten werden von der Gesellschaft getragen. Die Gesellschaft wird die Rückreise in Abstimmung mit Ihnen organisieren.

Sec. 7
Other provisions

Unless otherwise expressed in the Letter at hand, the current provisions concerning employment law as well as the statutory provisions remain in effect.

§ 7
Sonstige Regelungen

Soweit nicht in der vorliegenden Entsendebestätigung etwas Abweichendes geregelt ist, verbleibt es bei den bisherigen arbeitsvertraglichen Regelungen.

Sec. 8
Authoritative version

Both the English and the German version of this Letter are binding. In case of deviations in the interpretation, the German version shall prevail.

§ 8
Maßgebliche Fassung

Sowohl die englische als auch die deutsche Version dieser Bestätigung sind bindend. Sollten unterschiedliche Auslegungsmöglichkeiten zwischen den beiden Versionen bestehen, so geht die deutsche Version vor.

Kind regards

/s/ Ryan Barrett
atai Life Sciences US, Inc.
Ryan Barrett
General Counsel

Accepted

Akzeptiert

/s/ Srinivas Rao

Srinivas Rao

Exhibit 10.4

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Agreement"), is made and entered into as of the 10th of May 2023 (the "Effective Date"), by and between atai Life Sciences US, Inc. a Delaware corporation (the "Company") and Anne Johnson (the "Executive"). The Company and the Executive may each be referred to in this Agreement individually, as a "Party" and collectively, as the "Parties."

RECITALS

A. The Company and Executive previously entered into that certain Employment Agreement, dated as of January 1, 2021 (the "Prior Agreement").

B. The Company desires to continue to benefit from the services of Executive, and Executive desires to continue to render such services, on the terms and conditions set forth in this Agreement.

C. Effective as of the Effective Date, this Agreement will supersede the Prior Agreement in all respects except as otherwise expressly stated in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the compensation and benefits provided by the Company and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Executive, intending to be legally bound, hereby agree as follows, effective on the Effective Date:

1. Employment. The Company shall continue to employ the Executive, and the Executive shall be employed by the Company, under the terms and conditions set forth in this Agreement.

2. Term. The Executive shall be employed at will, meaning that either the Company or the Executive may terminate the Agreement and the Executive's employment at any time for any reason or no reason, with or without cause, subject to the terms of this Agreement. The period of Executive's employment hereunder is hereinafter referred to as the "Term".

3. Position and Duties. During the Term, the Executive shall continue to have the position of Chief Accounting Officer of the Company, and shall have the duties and responsibilities commensurate with such position, as well as such other duties and responsibilities as the board of directors of the Company (the "Board of Directors" or the "Board"), may from time-to-time direct to the extent consistent with Executive's position and status as set forth above.

4. Obligations of Executive. The Executive shall devote the Executive's services to the Company and shall perform the Executive's duties faithfully and to the best of the Executive's

ability. The Executive shall devote the Executive's full working time and best efforts to the business and affairs of the Company and the Affiliates (as defined below) and will use best efforts and business judgment, skill and knowledge to the advancement of the Company's and Affiliates' interests and to the discharge of the Executive's duties and responsibilities under this Agreement. Executive shall not, at any time during Executive's employment with the Company, directly or indirectly, render any business, commercial, or professional services that are directly related to the business in which the Company or any Affiliates is now involved or becomes involved during the term of Executive's employment, to any other person, firm, or organization, nor will Executive engage in any other activities that conflict with Executive's obligations to the Company (or any of its Affiliates), without the prior approval of the Board of Directors. For purposes of this Agreement, "Affiliate" means any person in control of, controlled by or under common control with, the Company or atai Life Sciences N.V. (the "Parent"), or any of their respective subsidiaries, parent companies, or related companies, divisions, predecessors, successors, interests, assigns, and/or entities in which each has an ownership interest, and all persons acting by, through, under and/or in concert with any of foregoing.

4. Salary and Benefits. During the Term, in consideration of the Executive's agreement to be employed by the Company and for the services to be rendered under this Agreement, the Company agrees to provide compensation to the Executive as follows:

(a) Salary. During the Term, the Executive shall be paid an annual salary of $360,000 (as may adjusted from time to time in accordance herewith, the "Base Salary") payable in equal semi-monthly installments or otherwise in accordance with the Company's standard payroll cycle. Any increases in the Base Salary shall be determined in the sole discretion of the Board (and, for the avoidance of doubt, any increased Base Salary shall constitute "Base Salary" for all purposes hereof).

(b) Bonus. During the Term, the Executive shall be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Bonus") shall be targeted at 40% of the Base Salary (the "Target Bonus"). The Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the applicable date(s) of payment, except as provided in Section 7.

(c) Reimbursement of Expenses. During the Term, the Company shall reimburse the Executive for her reasonable business expenses incurred in the performance of Executive's duties under this Agreement in accordance with such policies as the Company may adopt from time to time.

(d) Benefits. During the Term, the Executive shall be eligible to participate in employee benefit plans, programs and arrangements available to employees of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time.

(e) Vacation. During the Term, the Executive is allowed to take as much leave as the Executive needs in accordance with Executive's manager and the flexible time-off policy of the Company, subject to modification at the Company's sole discretion from time to time. Thus, there is no accrued vacation time upon Executive's termination for any reason.

(f) Sick Leave. Executive will be eligible for sick time in accordance with Company policy, as modified from time to time in the Company's discretion. Currently, US-based employees are eligible for up to 80 working hours (10 days) of paid sick leave per calendar year, with up to ten (10) days carry over to a subsequent year, except as provided by applicable law. Sick leave is not paid out upon termination of employment, unless otherwise required by applicable law.

(g) Equity Grants. During the Term, the Executive will be eligible for grants of equity or equity-based awards under any equity compensation plans of Company and/or Parent as in effect from time to time at the discretion of the Boards and in accordance with the applicable equity compensation plan(s).

(h) Withholdings. The Company shall, in accordance with applicable law, deduct from the Base Salary and all other amounts payable by the Company under the provisions of this Agreement to the Executive, or, if applicable, to her estate, legal representatives or such other beneficiary designated in writing by the Executive, all social security taxes, all federal, state and municipal taxes and all other charges and deductions that now or hereafter are required by law to be charged on the compensation of the Executive or charged on cash benefits ("Tax" or "Taxes"), irrespective of whether the Company or Parent is required to deduct.

(i) Indemnification. The Executive shall be eligible for indemnification in accordance with the terms of the Company's or any Affiliates' organizational documents and any indemnification agreements entered into with the Executive, which indemnification shall remain in effect after the Term as it applies to the Executive's service to the Company to the same extent it applies to other executives of the Company.

5. Termination. Executive's employment hereunder may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances, and the Term will end on the Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by reason of Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 6(a)(ii)-(vi), either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 6(b), whichever is earlier.

(a) Circumstances. The Executive shall cease to be an employee of the Company upon the occurrence of any of the following events:

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause*. The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause*. The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason*. Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason*. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 6 (other than termination pursuant to Section 6(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided*, *however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 6, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 5(d); and (iii) any vested benefits owed to Executive under any qualified retirement plan or health and welfare benefit plan in which Executive was a participant in accordance with applicable law and the provisions of such plan.

Except as otherwise expressly required by law (e.g., COBRA) or applicable plan, program, or arrangement or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 6(c) or Section 7, as applicable

(d) Deemed Resignation. If the Executive's employment with Company terminates for any reason, Executive shall be deemed to have resigned at that time from any and all positions that she may have held with Company or any Affiliates, as designated by Company or any Affiliates, or any other positions that Executive held on behalf of Company or any Affiliates. If, for any reason, this Section 6(d) is deemed insufficient to effectuate such resignation, following a reasonable opportunity to review, Executive hereby authorizes Company and any Affiliates to execute any documents or instruments consistent herewith which Company may deem necessary or desirable to effectuate such resignation or resignations, and to act as her attorney-in-fact. The Company will provide Executive with a copy of such documents.

(e) Mitigation. The Executive shall not be required to mitigate damages, or the amount of any payment provided for under this Agreement by seeking other employment or otherwise after the termination of her employment hereunder, and any amounts earned by the Executive, whether from self-employment, as a common-law employee or otherwise, shall not reduce the amount of any payments under Section 7 otherwise payable to the Executive. For the avoidance of doubt, this Section 6(e) shall not affect Section 7(b)(ii) or Section 7(c)(ii).

6. Payments upon Termination.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 6(a)(i) or Disability pursuant to Section 6(a)(ii), or pursuant to Section 6(a)(iii) for Cause, or pursuant to Section 6(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 6(c). In addition, in the event Executive's employment terminates for Cause or due to Executive's resignation from the Company without Good Reason, any unexercised option awards (whether vested or unvested) held by Executive under any equity compensation plans of the Company and/or Parent will expire and be forfeited as of the Date of Termination.

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive's employment is terminated by the Company without Cause pursuant to Section 6(a)(iv), or pursuant to Section 6(a)(v) due to Executive's resignation with

Good Reason, then except as otherwise provided under Section 7(c) and subject to Executive signing on or before the 21st day (or, in the event of a group termination, the 45th day) following Executive's Date of Termination, and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release") and Executive's continued compliance with Section 9, Executive shall receive, in addition to payments and benefits set forth in Section 6(c), the following:

(i) an amount equal to 0.75 times the Executive's then-current Base Salary, payable in the form of salary continuation in regular installments over the nine (9) month period following the Date of Termination (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) subject to Executive's eligibility and election of continuation coverage of group health coverage pursuant to COBRA, reimbursement of the cost of continuation coverage of group health coverage during the Severance Period; provided, that such reimbursement will cease if Executive receives coverage under a subsequent employer's group health plan prior to the end of such Severance Period, and provided, further, that, notwithstanding the foregoing, if the Company determines that it cannot provide the benefit required by this clause (b)(ii) without potentially violating applicable law or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and the Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and end on the earliest of (x) the last day of the Severance Period, (y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA and (z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility); and

(iii) the unpaid portion of the Annual Bonus, if any, for any calendar year ending prior to the calendar year in which the Date of Termination occurs (as determined by the Board in good faith for the performance year), which amount will be paid no later than April 30th of the year in which the Date of Termination occurs.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 7(b), in the event Executive's employment is terminated by the Company without Cause pursuant to Section 6(a)(iv), or pursuant to Section 6(a)(v) due to Executive's resignation with

Good Reason, in either case, on or within twelve (12) months following the date of a Change in Control, subject to Executive signing on or before the 21st day (or, in the event of a group termination, 45th day) following Executive's Date of Termination, and not revoking, the Release and Executive's continued compliance with Section 9, Executive shall receive, in lieu of the payments and benefits set forth in Section 7(b), the following:

(i) an amount in cash equal to the sum of (A) 12 months of the Executive's then-current Base Salary, and (B) the then-current Target Bonus, payable in a lump sum within sixty (60) days following the Date of Termination;

(ii) the benefits set forth in Section 7(b)(ii), provided that solely for this purpose, "Severance Period" shall mean the 12-month period following the Date of Termination; and

(iii) all unvested equity or equity-based awards that vest solely based on the passage of time and are then held by the Executive under any Company equity compensation plans shall immediately become 100% vested (with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement), and the time period that the Executive may have to exercise any stock options shall be extended for a period equal to the shorter of (x) 12 months or (y) the remaining term of the applicable stock option.

7. Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) the commission by the Executive of, or indictment of the Executive for, (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, or intentional fraud ("indictment," for these purposes, meaning an indictment, probable cause hearing or any other procedure pursuant to which an initial determination of probable or reasonable cause with respect to such offense is made);

(ii) the Executive's gross negligence, willful misconduct or repeated insubordination with respect to the Company or any Affiliate;

(iii) the Executive's use of alcohol or illegal drugs in a manner that impairs the performance of the Executive's obligations under this Agreement;

(iv)the Executive has engaged in misconduct that violates any applicable state or federal law prohibiting workplace harassment, including but not limited to sexual harassment, and/or discrimination, or that violates any written policy of the Company adopted to prevent workplace harassment or discrimination;

(v) the Executive's engagement in conduct which the Executive knows or reasonably should have known would cause the Company to violate any state or federal law; or

(vi)(A) repeated failure of Executive to substantially perform her employment duties hereunder, (B) the Executive's material breach of any of the material obligations of the Executive under this Agreement if such breach is not cured within five (5) days of notice of such breach to the Executive from the Board of Directors, or (C) Company's severe financial distress, whereby the Company is in the process of winding down its business and Executive's employment is terminated in connection with such winding down.

(b) Change in Control. "Change in Control" shall have the following meaning for purposes of this Agreement:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than Parent, any Affiliate, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of Parent or any Affiliate), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of Parent representing fifty percent (50%) or more of the combined voting power of Parent's then outstanding securities having the right to vote in an election of the Board of Directors of Parent ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from Parent); or

(ii) the consummation of (A) any consolidation or merger of Parent where the shareholders of Parent, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than fifty percent (50%) of the voting shares of Parent issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of Parent.

Notwithstanding the foregoing, a Change in Control shall not be deemed to have occurred (x) as a result of a financing transaction involving Parent's equity securities, (y) as a result of a transaction that occurs to change the domicile of Parent, or (z) for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by Parent that, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to fifty percent (50%) or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from Parent) and immediately thereafter beneficially owns fifty percent (50%) or more of the combined voting power of all of the then outstanding Voting Securities, then a Change in Control shall be deemed to have occurred for purposes of the foregoing clause (i). Notwithstanding the foregoing, a Change in Control shall not have occurred unless the transaction or event constituting the Change in Control would also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) under Section 409A (defined below).

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Disability. "Disability" shall mean termination because the Executive is unable due to a physical or mental condition to perform the essential functions of Executive's position with or without reasonable accommodation for six (6) months in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Executive's employment is terminated based on the Executive's Disability, then the Executive shall not be entitled to any severance payments or benefits, except as provided in Section 6(c).

(e) Good Reason. "Good Reason" shall mean the Company's material breach of any of the material obligations of the Company under this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive resigns within ninety (90) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, (b) Executive has provided the Company, within sixty (60) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (c) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (d) the Company shall have failed to so cure within such period.

8. Restrictive Covenants.

(a) Confidentiality. The Executive has previously executed that certain proprietary Confidentiality and Developments Agreement, dated as of December 3, 2020 (the "Confidentiality and Developments Agreement"), which remains in full force and effect and is hereby made a part of this Agreement.

(b) Noncompetition.

(i) In consideration for the severance opportunities set forth in Section 7, amongst other terms, which Executive acknowledges and agrees is fair and reasonable consideration independent of Executive's continued employment, during the Term and for a period (the "Non-Competition Restricted Period") of one (1) year after the Date of Termination (or for a period of two (2) years after the Date of Termination if the Executive breaches the Executive's fiduciary duty to the Company or misappropriates Company property or proprietary information, in each case as reasonably determined by the Company), Executive shall not, without the Company's prior written consent, whether individually, as a director, manager, member, stockholder, partner, owner, employee, consultant, advisor, agent, or in any other capacity, other than on behalf of the Company or any Affiliates, directly or indirectly, organize, establish, own, operate, manage, control, engage in, participate in, invest in, permit Executive's name to be used by, act as a consultant or advisor to, render services for (alone or in association with any person, firm, corporation or business organization), or otherwise assist any person that engages in any business which competes with any portion of the Competitive Business (as defined below) anywhere in the world (the "Non-Competition Covenant"). Notwithstanding the prior sentence, nothing shall prevent Executive from owning, for passive investment purposes not intended to circumvent this Agreement, less than three percent (3%) of the publicly-traded common equity securities of any such person. Executive agrees and acknowledges that the Executive has the means to support Executive and Executive's dependents other than by violating the provisions of this clause (b), and the provisions of this clause (b) will not impair such ability. For purposes of this Section 9, "Competitive Business" shall mean the research, development and/or commercialization (collectively, "Develop") of any compound that has psychedelic, entactogenic and/or oneirophrenic properties, which is being Developed for the treatment of a mental health disease or disorder, and which Development would be competitive to any business conducted by the Company or any Affiliate or any business of which Executive knows the Company or any Affiliate has specific plans to engage in on the Date of Termination.

(ii) At any time, the Company may in its sole discretion elect to waive any or part of the Non-Competition Covenant, provided any such waiver is expressly stated in writing by a duly authorized Company representative. Such written waiver shall be deemed effective when mailed to the Executive

at the Executive's last known address or when given to the Executive in person, or, if during the Executive's employment with the Company, if emailed to the Executive at the Executive's Company-provided email address.

(iii)The Executive acknowledges that the Executive has been advised to consult with an attorney in connection with this clause (b).

(c) Nonsolicitation. During the Term and for a period of two (2) years after the Date of Termination, Executive will not directly or indirectly (i) solicit any individual who, at the time of the solicitation is, or within the six (6) months prior to the Date of Termination was, an employee of or consultant to Company or any Affiliate to terminate his or her relationship with the Company or any Affiliate; or (ii) attempt to induce any clients, licensors, licensees or customers of Company or any Affiliate to terminate, breach or materially change any contractual or other relationship with Company or any Affiliate.

(d) Use of Material Undisclosed Information. The Executive acknowledges that it is the policy of the Company that all employees are prohibited from benefiting from the possession of material undisclosed information concerning the Company or any Affiliates, providers or business partners (in each case provided they are listed on a national or international securities exchange) with respect to trading in the public securities markets. The Executive covenants and agrees that he will abide by such policy.

(e) Reasonable Restrictions. The Executive further acknowledges and agrees that the provisions of this Section 9 are reasonable and properly required for the adequate protection of the Competitive Business. Executive represents and warrants that (i) the restrictive provisions of this Section 9 will not substantially impair Executive's ability to earn a livelihood, nor will such provisions cause Executive undue hardship, and (ii) Executive has fully and carefully read this Agreement and has been advised by the Company to consult with an attorney of Executive's choice and that Executive fully understands and agrees with the provisions of this Agreement, including this Section 9.

(f) Blue Penciling. If, at the time of enforcement of any of the provisions of this Section 9, a court shall hold that the duration, scope, geographic area or other restrictions stated herein are unreasonable under circumstances then existing, Executive and the Company agree that the maximum duration, scope, geographic area or other restrictions deemed reasonable under such circumstances by such court shall be substituted for the stated duration, scope, geographic area or other restrictions.

9. Cooperation.

(a) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of

information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's continued employment with the Company and the performance of the Executive's duties for the Company or any Affiliates will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company or any Affiliates, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company or any Affiliates any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(b) Litigation and Regulatory Cooperation. During and after the Executive's employment with the Company, the Executive shall reasonably cooperate with the Company and any Affiliate in the defense or prosecution of any claims or actions now in existence or that may be brought in the future against or on behalf of the Company or any Affiliate that relate to events or occurrences that transpired while the Executive was employed by the Company provided that such cooperation after the termination of Executive's employment with the Company does not otherwise interfere with the Executive's subsequent employment and/or engagement with a subsequent employer and/or third parties. The Executive's reasonable cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company and any Affiliate at mutually convenient times. During and after the Term, the Executive also shall cooperate reasonably with the Company and any Affiliate in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company or the applicable Affiliate shall reimburse the Executive for any reasonable out-of-pocket expenses (including reasonable legal fees) incurred in connection with the Executive's performance of obligations pursuant to this Section 10(b).

(c) Injunction. The Executive acknowledges that any material breach by Executive of Executive's obligations under this Agreement, including but not limited to the restrictions set forth in Section 9 hereof, would result in irreparable injury to the Company or an Affiliate. The Company or the applicable Affiliate shall, therefore, be entitled, without restricting the Company or such applicable Affiliate(s) from other legal and equitable remedies, to injunctive and other equitable relief to prevent or restrain the breach of this Agreement and to withhold compensation and benefits from the Executive if he fails to comply with this Agreement. Nothing in this Section shall be deemed to restrict any other remedy or right the Company, any Affiliate or the Executive may have for any other breach of this Agreement.

(d) Governing Law; Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 9 of this Agreement, the Parties

hereby consent to the jurisdiction of the State of New York and County of New York. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10.Assignment. This Agreement is personal to Executive, and Executive may not assign or delegate any of Executive's rights or obligations under this Agreement without first obtaining the written consent of the Company. The Company may assign and delegate its rights and obligations under this Agreement, in each case in whole but not in part, without the prior consent of the Executive in the event that, and only in the event that, (a) the Company shall effect a reorganization, consolidate with, or merge into, any other corporation, partnership, organization or other entity, or transfer all or substantially all of its properties or assets to any other corporation, partnership, organization or other entity, (b) such corporation, partnership, organization or other entity referred to in the preceding clause "(a)" including without limitation any affiliate thereof shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party to this Agreement.

11.Notices. All notices required under this Agreement shall be given by personal delivery deemed given on the date of receipt, or by postage prepaid certified or registered mail, return receipt requested, addressed to the Company or to the Executive as follows, or to such other address as either Party shall notify the other by like notice:

If to the Company: ATAI Life Sciences US Inc.

c/o WeWork

524 Broadway, 11th Floor

New York, NY 10012

Attn: General Counsel

with a copy to (by email)
Kristina Beirne, Esq., Dentons US, LLP (kristina.beirne@dentons.com)

If to the Executive: Anne Johnson
10412 McCall Road
Georgetown, OH 45121

If sent by mail, such notice shall be deemed to have been given on the date of delivery set forth on the registered or certified mail receipt or upon the third (3rd) day after mailing if delivery is refused.

12.Expenses of Enforcement. In the event that any suit or legal proceeding is brought to enforce any provision of this Agreement, each party shall be responsible for their expenses, including reasonable attorneys' fees and costs.

13.Advice of Counsel. The Executive acknowledges that, in executing this Agreement, the Executive has had the opportunity to seek the advice of independent legal counsel, and has read and understood all of the terms and provisions of this Agreement. This Agreement shall not be construed against any Party by reason of the drafting or preparation hereof.

14.Section 409A. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"), and the Parties hereby agree to amend this Agreement as and when necessary or desirable to conform to or otherwise properly reflect any guidance issued under Section 409A after the date hereof without violating Section 409A. In case any one or more provisions of this Agreement fails to comply with the provisions of Section 409A, the remaining provisions of this Agreement shall remain in effect, and this Agreement shall be administered and applied as if the non-complying provisions were not part of this Agreement. The Parties in that event shall endeavor to agree upon a reasonable substitute for the non-complying provisions, to the extent that a substituted provision would not cause this Agreement to fail to comply with Section 409A, and, upon so agreeing, shall incorporate such substituted provisions into this Agreement. A termination of the Executive's employment hereunder shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amount or benefit constituting "deferred compensation" under Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." In the event that any payment or benefit made hereunder or under any compensation plan, program or arrangement of the Company would constitute payments or benefits pursuant to a non-qualified deferred compensation plan within the meaning of Section 409A and, at the time of the Executive's "separation from service" the Executive is a "specified employee" within the meaning of Section 409A, then any such payments or benefits shall be delayed until the six-month anniversary of the date of Executive's "separation from service". Each payment made under this Agreement shall be designated as a "separate payment" within the meaning of Section 409A. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A. All reimbursements for expenses paid pursuant hereto that constitute taxable income to the Executive shall in no event be paid later than the end of the calendar year next following the calendar year in which the Executive incurs such expense or pays such related tax. Unless otherwise permitted by Section 409A, the right to reimbursement or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit and the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, respectively, in any other taxable year.

15.Section 280G.

(a) Notwithstanding anything contained in this Agreement to the contrary, in the event that any payment or benefit received or to be received by the Executive (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement) (all such payments and benefits being hereinafter referred to as the "Total Payments") would be subject (in whole or part), to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then, after taking into account any reduction in the Total Payments provided by reason of Section 280G of the Code in any other plan, arrangement or agreement, then such remaining Total Payments shall be reduced, to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments) is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income taxes on such Total Payments and the amount of Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) For purposes of determining whether and the extent to which the Total Payments will be subject to the Excise Tax, (i) no portion of the Total Payments the receipt or enjoyment of which Executive shall have waived at such time and in such manner as not to constitute a "payment" within the meaning of Section 280G(b) of the Code shall be taken into account; (ii) no portion of the Total Payments shall be taken into account which, in the written opinion of an independent, nationally recognized accounting firm (the "Independent Advisors") selected by the Company, does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) and, in calculating the Excise Tax, no portion of such Total Payments shall be taken into account which, in the opinion of Independent Advisors, constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation; and (iii) the value of any non-cash benefit or any deferred payment or benefit included in the Total Payments shall be determined by the Independent Advisors in accordance with the principles of Sections 280G(d)(3) and (4) of the Code.

16. Miscellaneous.

(a) This Agreement shall be governed by, and construed exclusively in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law rules to the contrary. Each Party submits to the nonexclusive jurisdiction of any United States District Court located in New York, New York and of any New York state court sitting in New York, New York for purposes of all legal proceedings arising out of or relating to this Agreement or the transactions

contemplated hereby. Each Party irrevocably waives any objection which it may now or hereafter have to the laying of venue in any proceeding brought in such a court, and any claim that any such proceeding was brought in an inconvenient forum.

(b) Should any provision of this Agreement be held invalid or unenforceable, the remainder of this Agreement shall not be affected and shall be enforceable to the fullest extent permitted at law or in equity.

(c) This Agreement (together with the Exhibits hereto, if any) contains the entire agreement between the Parties concerning the subject matter hereof and supersedes all prior conversations, proposals, negotiations, understandings and agreements, whether written or oral, concerning the subject matter hereof, including, the Prior Agreement, except as otherwise expressly specified in this Agreement.

(d) This Agreement shall not be amended, altered, changed, modified, supplemented or rescinded in any manner except by written agreement executed by both Parties expressly referring to this Agreement.

(e) No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving Party. The failure of any Party to require the performance of any term or obligation of this Agreement, or the waiver by any Party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

(f) This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

(g) The Parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Company or out of this Agreement, or the Executive's termination of employment or termination of this Agreement, may not be in the best interests of either the Executive or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The Parties agree that any dispute between the Parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided*, *however*, that this

dispute resolution provision shall not apply to any separate agreements between the Parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the New York metropolitan area. Any award made by such panel shall be final, binding and conclusive on the Parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; *provided*, *however*, that at the Executive's option, Executive may voluntarily pay up to one-half the costs and fees. The Parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Executive and the Company. The Parties each further agree that the arbitration provisions of this Agreement shall provide each Party with its **exclusive remedy**, and each Party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election of arbitration as the means for final settlement of all claims, **the Parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The Parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

[Signature page to follow]

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date set forth opposite their respective names below.

EXECUTIVE

Dated: May 11, 2023

/s/ Anne Johnson
Anne Johnson

atai Life Sciences US Inc.

Dated: May 12, 2023

By: /s/ Florian Brand
Name: Florian Brand
Title: CEO

|US-DOCS\137968368.1||

EXHIBIT A
SEPARATION AND RELEASE AGREEMENT

This Separation and Release Agreement ("Agreement") is made by and between Anne Johnson ("Executive") and atai Life Sciences US, Inc., a Delaware corporation (together with any successor, the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Amended and Restated Employment Agreement, dated as of _____, 202[ ] (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company or one if its affiliates, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section [7(b)/7(c)] of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [7(b)/7(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 6(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims.[1] Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action, relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising in any jurisdiction from any

[1] The Company reserves the right to revise this release language to account for applicable law.

omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims for wages, bonuses, incentive compensation, stock, stock options, vacation pay or any other compensation or benefits or any other claim arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Ohio Minimum Wage Law and the New York Labor Law and including but not limited to all provisions prohibiting discrimination and retaliation, and all provisions regulating wage and hour law); and

(i) any and all claims for attorneys' fees and costs.

Executive acknowledges that Executive has been advised of and is familiar with the provisions of California Civil Code Section 1542, which states:

> "A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if

known by him or her, would have materially affected his or her settlement with the debtor or released party."

Being aware of said code section, Executive hereby expressly waives any rights Executive may have thereunder, as well as under any other statutes or common law principles of similar effect.

Executive affirms that as of the date of Executive's signature below, no action or proceeding covered by this Section was pending against any of the Released Parties.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation and any right to receive an award for information provided thereunder, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company for discrimination (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from the Company or any Releasee for any alleged discriminatory treatment), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as of the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained Claims. This release further does not release claims for breach of Section 6(c) or Section [7(b)/7(c)] of the Employment Agreement. For the avoidance of doubt, this release does not restrict Executive from engaging in protected conduct, including, but not limited to, communication, cooperation with or providing information to, any federal, state or local government regulator, including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice, or the U.S. National Labor Relations Board, exercising any rights Employee may have under Section 7 of the National Labor Relations Act, and discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Employee has reason to believe is unlawful.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has [21/45][2] days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days

[2] Consistent with the Older Workers Benefit Protection Act, 45 days will be provided in the event of a group termination.

following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the [21/45] day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

5. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

6. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Section 12 and Section 17(a) and (g) of the Employment Agreement.

7. Effective Date. Executive has seven days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

8. Confidentiality of Separation Agreement. Executive has agreed that, except as may be required by law, Executive shall not disclose to any individual or entity the terms of this Agreement or the circumstances of Executive's separation from the Company; provided, however, that the foregoing shall not prohibit Executive from disclosing the terms and conditions of this Agreement to Executive's spouse, attorneys, and tax advisor (collectively, "Executive's Confidants"), on a need-to-know basis only, provided that Executive informs Executive's Confidants of this Section 8 and they agree to keep any such disclosed information strictly confidential. In the event any such disclosure is made in violation of this Section 8, any outstanding obligations of the Company hereunder shall immediately terminate, and any payments previously made by the Company hereunder shall be returned to the Company. Executive understands and agrees that this Section 8 is a material provision of this Agreement and that any breach of this Section 8 by Executive or Executive's Confidants shall be a material breach of this Agreement.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; (e) Executive is fully aware of the legal and binding effect of this Agreement; and (f) Executive has had [21/45] days to review this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated:

_____
Anne Johnson

ATAI LIFE SCIENCES US, INC.

Dated:

By:_____
Name: Florian Brand
Title: CEO

|US-DOCS\137968368.1||

Exhibit 10.28

CONSENT AND FOURTH AMENDMENT TO
LOAN AND SECURITY AGREEMENT

This **CONSENT AND FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Consent and Amendment**") is dated as of January 6, 2025 and is entered into by and among ATAI LIFE SCIENCES N.V., a public limited liability company (naamloze vennootschap) incorporated under the laws of the Netherlands, having its corporate seat (statutaire zetel) in Amsterdam, the Netherlands, its registered office at Wallstraße 16, 10179 Berlin, Federal Republic of Germany, and registered with the trade register of the Chamber of Commerce (handelsregister van de Kamer van Koophandel) under number 80299776 ("**Parent**"), ATAI LIFE SCIENCES AG, a stock corporation (Aktiengesellschaft) incorporated under the laws of Germany and registered with the commercial register of the local court of Munich under HRB 239201, with business address at Wallstraße 16, 10179 Berlin ("**ATAI Germany**", and together with Parent, ATAI Germany and each other Person party to the Loan Agreement as a borrower from time to time, individually or collectively, as the context may require, "**Borrower**"), ATAI LIFE SCIENCES US, INC., a Delaware corporation ("**ATAI US**"), Atai Therapeutics, Inc., a Delaware corporation ("**Atai Therapeutics**"), Atai Holdco, Inc., a Delaware corporation ("**Atai Holdco**"), Atai Therapeutics Holdings, Inc., a Delaware corporation ("**Atai Therapeutics Holdings**"), EmpathBio, Inc., a Delaware corporation ("**Empath**", and together with ATAI US, Atai Therapeutics, Atai Holdco, Atai Therapeutics Holdings, and any other Person party to the Loan Agreement from time to time as a guarantor, collectively, the "**Guarantors**" and each a "**Guarantor**"), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively referred to as the "**Lenders**" and each a "**Lender**") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, "**Agent**"). Capitalized terms used herein without definition shall have the same meanings given them in the Loan Agreement (as defined below).

RECITALS

A. Borrower, Guarantors, Agent and Lenders have entered into that certain Loan and Security Agreement dated as of August 9, 2022, among Borrower, Guarantors, Agent and Lenders (as amended by the First Amendment to Loan and Security Agreement dated as of March 13, 2023, as amended by the Second Amendment to Loan and Security Agreement, dated May 26, 2023, as amended by the Third Amendment to Loan and Security Agreement, dated August 14, 2024, and as further amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"), pursuant to which Lenders have agreed to extend and make available to Borrower certain advances of money.

B. Borrower has (i) notified Agent pursuant to Section 7.11 that ATAI Germany intends to change its legal form from a German stock corporation (*Aktiengesellschaft – AG*) into a German limited liability company (*Gesellschaft mit beschränkter Haftung – GmbH*) (the "**ATAI Germany Conversion**") and (ii) requested that Agent and Lenders agree to consent to the ATAI Germany Conversion.

C. In accordance with Section 11.3 of the Loan Agreement, Borrower has requested that Agent and Lenders agree to amend certain provisions of the Loan Agreement in connection with the ATAI Germany Conversion.

D. Agent and Lenders have agreed to consent to the ATAI Germany Conversion and amend the Loan Agreement upon the terms and conditions more fully set forth herein.

E. In connection with the ATAI Germany Conversion, Parent, Company and Agent have agreed to enter on or about the date hereof also into (i) a German law amendment agreement relating to certain German Security Documents (the "**German Amendment Agreement**") and (ii) an English law amendment agreement relating to the English Share Charge (the "**UK Amendment Agreement**"), each providing for, among other things, the inclusion of German limitation language in connection with the ATAI Germany Conversion.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing Recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. CONSENT TO THE ATAI GERMANY CONVERSION. Subject to the occurrence of the Consent and Amendment Effective Date (as defined below), Agent and Lenders hereby consent to the ATAI Germany Conversion.

2. AMENDMENTS. With effect upon the occurrence of each of the following: (i) the completion of registration of ATAI Germany Conversion with the competent commercial register of ATAI Germany (the "**Conversion Date**") and (ii) the Consent and Amendment Effective Date (as defined below):

2.1 Section 12.9 of the Loan Agreement is amended and restated in its entirety as follows:

"12.9 German Guarantee Limitation

12.9.1 In this Section 12.9

"**Conversion Date**" means the date on which the change of the legal form of ATAI Germany from a German stock corporation (*Aktiengesellschaft – AG*) into a German limited liability company (*Gesellschaft mit beschränkter Haftung – GmbH*) is registered with the competent commercial register of ATAI Germany.

"**Guarantee**" means the guarantee given pursuant to this Section 12 (Guarantee).

"**Net Assets**" means an amount equal to the sum of the amounts of ATA Germany's assets (consisting of all assets which correspond to the items set forth in section 266 para 2 A, B, C, D and E of the German Commercial Code (*Handelsgesetzbuch,* "**HGB**")) less the aggregate amount of its liabilities (consisting of all liabilities and liability reserves which correspond to the items set forth in section 266 para 3 B, C, D and E HGB), save that any obligations *(Verbindlichkeiten)* of ATAI Germany:

(a) incurred in violation of the provisions of any of the Loan Documents; or

(b) subordinated pursuant to section 39 para 1 no. 5 or para 2 of the German Insolvency Code (*InsO*) to any Indebtedness outstanding under this Agreement (including indebtedness in respect of guarantees for Indebtedness which is so subordinated),

shall be disregarded. The Net Assets shall be determined in accordance with the generally accepted accounting principles applicable from time to time in Germany (*Grundsätze ordnungsmäßiger Buchfiihrung*).

"**Protected Capital**" means, in relation to ATAI Germany, the aggregate amount of:

(a) its share capital (*Stammkapital*) as registered in the commercial register (*Handelsregister*) provided that any increase which is registered after the Conversion Date shall not be taken into account unless (i) such increase has been effected with the prior written consent of Agent (even if such increase is permitted under this Agreement or any other Loan Document) and (ii) only to the extent it is fully paid up; and

(b) its amount of profits (*Gewinne*) or reserves (*Rücklagen*) which are not available for distribution to its shareholder(s) in accordance with section 268 para 8 HGB.

12.9.2 As long as ATAI Germany is incorporated as a company with limited liability (*Gesellschaft mit beschränkter Haftung*) under German law, Agent and the Lenders agree, other than in accordance with the procedure set out in Section 12.9.3 to Section 12.9.5 below, not to enforce the Guarantee if and to the extent that:

(a) the Guarantee secures the obligations or liabilities of a Loan Party which is a shareholder of ATAI Germany or an affiliated company *(verbundenes Unternehmen)* of such shareholder within the meaning of section 16, 17 or 18 of the German Stock Corporation Act *(Aktiengesetz)* (other than ATAI Germany and its Subsidiaries) (an "**Up-Stream or Cross-Stream Security**"); and

(b) payment under the Guarantee would otherwise:

(i) have the effect of reducing ATAI Germany's Net Assets to an amount that is lower than the amount of its Protected Capital or, if the amount of the Net Assets is already lower than the amount of its Protected Capital, the effect of causing the Net Assets to be further reduced; and

(ii) thereby give rise to a violation of the capital maintenance requirement as set out in section 30 para 1 of the German Limited Liability Companies Act (*Gesetz betreffend die Gesellschaften mit beschränkter Haftung*).

12.9.3 The limitations set out in Section 12.9.2 above only apply if and to the extent that:

(a) within five (5) Business Days after Agent or a Lender has made a demand under the Guarantee, ATAI Germany has confirmed in writing (signed by its managing director(s)) to Agent):

(i) to what extent the Guarantee is an Up-Stream or Cross-Stream Security;

(ii) which amount of such Up-Stream or Cross-Stream Guarantee cannot be enforced as it would cause the Net Assets of ATAI Germany to fall below its registered

share capital (*Stammkapital*) or increase an existing shortage of its share capital (*Stammkapital*), and such confirmation is supported by detailed calculations and evidence reasonably satisfactory to Agent (the "**Management Determination**"); and

(b) if the Management Determination is contested by Agent or a Lender, within fourteen (14) Business Days from the date of such contest Agent receives an up-to-date balance sheet of ATAI Germany drawn up by auditors of international standard and reputation appointed by ATAI Germany, in consultation with Agent, with a determination and detailed calculation by such auditors (the "**Auditors' Determination**") showing the amount that would have been necessary on the date Agent or a Lender has made a demand under the Guarantee to maintain its registered share capital (*Stammkapital*) or to avoid the increase of an existing shortage of its registered share capital (taking into account the adjustments set out in this Section 12.9). ATAI Germany shall fulfil its obligations under the Guarantee and Agent and the Lenders shall be entitled to enforce the Guarantee in an amount which would, in accordance with the Auditor's Determination, not be necessary to maintain the registered share capital (*Stammkapital*) of ATAI Germany or avoid the increase of an existing shortage of its registered share capital.

12.9.4 If Agent and/or a Lender disagrees with the Auditor's Determination, it shall be entitled to make a demand under a Guarantee up to the amount which is undisputed between itself and ATAI Germany in accordance with the provisions of Section 12.9.3 above. In relation to the amount which is disputed, Agent shall be entitled to further pursue the Secured Parties' claims (if any) and ATAI Germany shall be entitled to prove that this amount is necessary for maintaining its registered share capital (*Stammkapital*) subject to the provisions of this Section 12.9.

12.9.5 If ATAI Germany claims in accordance with the provisions of Section 12.9.3 above that the Guarantee can only be enforced in a limited amount, it shall promptly (*unverzüglich*) realize, to the extent legally permitted and commercially justifiable with regard to costs and efforts involved, any and all of its assets that are shown in the balance sheet with a book value (*Buchwert*) that is significantly lower than the market value of such asset if such asset is not essential for ATAI Germany's business (*nicht betriebsnotwendiges Vermögen*) or, to the extent that any such asset is essential for its business, if such realization does not affect its ability to use that asset or the relevant part of its business can be carried on from other sources without use of such asset, following which its Net Assets shall be re-calculated and notified to Agent within fourteen (14) days taking into account the realized proceeds.

12.9.6 The limitations set out in Section 12.9.2 shall not apply:

(a) to the extent the Guarantee secures any amounts outstanding under any Loan Document in relation to any financial accommodation made

available under such Loan Document to any Borrower and on-lent or otherwise made available to ATAI Germany or any of its Subsidiaries and such amounts have not yet been repaid prior to Agent or a Lender making a demand under the Guarantee;

(b) if ATAI Germany is party to a domination agreement (*Beherrschungsvertrag*) with the Loan Party whose obligations are being secured as dominating entity unless and to the extent ATAI Germany evidences to Agent and the Lenders that at the time of enforcement of the Up-Stream or Cross-Stream Guarantee it will as a result of the enforcement of the Up-Stream or Cross-Stream Guarantee not acquire a valuable (*vollwertig*) claim for loss compensation pursuant to section 302 of the German Stock Corporation Act (*Aktiengesetz*); or

(c) if and to the extent the managing directors of ATAI Germany would not suffer personal or criminal liability as a result of ATAI Germany granting the Guarantee.

12.9.7 No reduction of the amount enforceable pursuant to this Section 12.9.2 will prejudice the right of the Secured Parties to continue to enforce the Guarantee (subject always to the operation of the limitations set out in this Section 12.9 at the time of such enforcement) until full satisfaction of the Guaranteed Obligations."

3. Loan Parties' Representations And Warranties. Each Loan Party represents and warrants that:

3.1 Immediately upon giving effect to this Consent and Amendment, (i) the representations and warranties contained in the Loan Documents are true and correct in all material respects except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date and (ii) no default or Event of Default has occurred and is continuing with respect to which such Loan Party has not been notified in writing by Agent or Lenders.

3.2 Each of the Loan Parties has the corporate power and authority to execute and deliver this Consent and Amendment and to perform its obligations under this Consent and Amendment and the Loan Agreement, as amended by this Amendment.

3.3 The execution and delivery by the Loan Parties of this Amendment and the performance by each of the Loan Parties of its obligations under this Consent and Amendment and the Loan Agreement, as amended by this Amendment, have been duly authorized by all necessary corporate action on the part of such Loan Party.

3.4 This Consent and Amendment has been duly executed and delivered by each Loan Party and is the binding obligation of such Loan Party, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

3.5 As of the date hereof, it has no defenses against the obligations to pay any amounts under the Secured Obligations. Each Loan Party acknowledges that each of Agent and the Lenders has, as of the date hereof, acted in good faith and has conducted in a commercially reasonable manner its relationships with the Loan Parties in connection with this Consent and Amendment and in connection with the Loan Documents.

Each Loan Party understands and acknowledges that each of Agent and the Lenders is entering into this Consent and Amendment in reliance upon, and in partial consideration for, the above representations and warranties, and agrees that such reliance is reasonable and appropriate.

4. Limitation. The consent and amendments set forth in this Consent and Amendment shall be limited precisely as written and shall not be deemed (a) to be a waiver or modification of any other term or condition of the Loan Agreement or of any other instrument or agreement referred to therein or to prejudice any right or remedy which Agent and/or Lenders may now have or may have in the future under or in connection with the Loan Agreement (as amended hereby) or any instrument or agreement referred to therein; or (b) to be a consent to any future amendment or modification or waiver to any instrument or agreement the execution and delivery of which is consented to hereby. Except as expressly amended hereby, the Loan Agreement shall continue in full force and effect.

5. Conditions to Consent and Amendment Effective Date. This Consent and Amendment shall become effective upon the satisfaction of all of the following conditions precedent in form and substance reasonably satisfactory to Agent (the date of satisfaction of all such conditions precedent, the "**Consent and Amendment Effective Date**"):

5.1 Effective Date. The Effective Date (as defined in the German Amendment Agreement) shall have occurred.

5.2 [Reserved].

5.3 Schedule 1 to Loan Agreement. The Agent shall have received an updated Schedule 1 (Entity Designations; Equity Interests; Instruments; Consents) to the Loan Agreement, as in effect as of the Conversion Date.

5.4 Representations and Warranties. The representations and warranties set forth in the Loan Agreement shall be true and correct in all material respects on and as of the Conversion Date.

5.5 Payment of Lenders' Expenses. The Loan Parties shall have paid all reasonable Lenders' expenses (including all reasonable attorneys' fees and reasonable expenses) incurred through the Consent and Amendment Effective Date for the documentation and negotiation of this Consent and Amendment, the German Amendment Agreement, the UK Amendment Agreement, and each other document mentioned in the German Amendment Agreement and/or entered into or delivered in connection with the ATAI Germany Conversion, in each case, to the extent invoiced on or prior to the Consent and Amendment Effective Date.

6. Release. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and

irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which such Loan Party, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time prior to the execution of this Consent and Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Each Loan Party understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Each Loan Party agrees that no fact, event, circumstance, evidence or transaction existing prior to the execution of this Consent and Amendment which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Each Loan Party waives the provisions of California Civil Code section 1542, which states:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

7. Counterparts. This Consent and Amendment may be signed in any number of counterparts, and by different parties hereto in separate counterparts, with the same effect as if the signatures to each such counterpart were upon a single instrument. All counterparts shall be deemed an original of this Consent and Amendment. This Consent and Amendment may be executed by facsimile, portable document format (.pdf) or similar technology signature, and such signature shall constitute an original for all purposes.

8. Incorporation By Reference. The provisions of Section 11 of the Loan Agreement shall be deemed incorporated herein by reference, *mutatis mutandis*.

9. Reaffirmation. By executing and delivering a counterpart hereof, (i) each Loan Party hereby agrees that all Advances incurred by such Loan Party shall be secured by the Collateral pursuant to the applicable Loan Documents in accordance with the terms and provisions thereof and (ii) each Loan Party hereby (A) agrees that, notwithstanding the effectiveness of this Consent and Amendment, after giving effect to this Consent and Amendment, the Loan Documents continue to be in full force and effect, (B) agrees that all of the Liens and security interests created and arising under the Loan Documents remain in full force and effect on a continuous basis, and the perfected status and priority of each such Lien and security interest continues in full force and effect on a continuous basis, unimpaired, uninterrupted and undischarged, as collateral security for its obligations, liabilities and indebtedness under the Loan Agreement to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Consent and Amendment) and (C) affirms and confirms all of its

obligations, liabilities and indebtedness under the Loan Agreement and each other Loan Document, in each case after giving effect to this Consent and Amendment, including the pledge of and/or grant of a security interest in its assets as Collateral pursuant to the Loan Documents to secure such Secured Obligations, all as provided in the Loan Documents, and acknowledges and agrees that such obligations, liabilities, guarantee, pledge and grant continue in full force and effect in respect of, and to secure, such Secured Obligations under the Loan Agreement and the other Loan Documents, in each case, to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Consent and Amendment).

[Signature Page Follows]

In Witness Whereof, the parties have duly authorized and caused this Consent and Amendment to be executed as of the date first written above.

BORROWER:

ATAI LIFE SCIENCES N.V.

Signature: /s/ Anne Johnson

Print Name: Anne Johnson

Title: Chief Financial Officer

ATAI LIFE SCIENCES AG

Signature: /s/ Anne Johnson

Print Name: Anne Johnson

Title: Chief Financial Officer

GUARANTORS:

ATAI LIFE SCIENCES US, INC.,
ATAI THERAPEUTICS, INC.,
ATAI HOLDCO, INC.,
ATAI THERAPEUTICS HOLDINGS, INC., and
EMPATHBIO, INC.

Signature: /s/ Anne Johnson

Print Name: Anne Johnson

Title: Chief Financial Officer

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: CFO

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: CFO

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

Exhibit 19.1

ATAI LIFE SCIENCES N.V.
INSIDER TRADING COMPLIANCE POLICY

Federal and state laws prohibit trading in the securities of a company while in possession of material nonpublic information and in breach of a duty of trust or confidence. These laws also prohibit anyone who is aware of material nonpublic information from providing this information to others who may trade. Violating such laws can undermine investor trust, harm ATAI Life Sciences N.V.'s reputation, and result in your dismissal from ATAI Life Sciences N.V. (together with its subsidiaries, within the meaning of Book 2, Section 24(a) of the Dutch Civil Code, the "***Company***") or even serious criminal and civil charges against you and the Company. The Company reserves the right to take disciplinary or other measure(s) it determines in its sole discretion to be appropriate in any particular situation, including disclosure of wrongdoing to governmental authorities.

This Insider Trading Compliance Policy (this "***Policy***") consists of seven sections:

- Section I: Persons Covered;
- Section II: Statement of Policies Prohibiting Insider Trading;
- Section III: Explanation of Insider Trading;
- Section IV: Statement of Procedures to Prevent Insider Trading;
- Section V: Prohibited Transactions;
- Section VI: Rule 10b5-1 Trading Plans;
- Section VII: Policy Administration; and
- Section VIII: Certification of Compliance.

I. Persons Covered

This Policy applies to all officers, directors, and employees of the Company. For purposes of this Policy, "officers" refer to those individuals who meet the definition of "officer" under Section 16 of the Securities Exchange Act of 1934 (as amended, the "***Exchange Act***"). Individuals subject to this Policy are responsible for ensuring that members of your household also comply with this Policy. This Policy also applies to any entities you control, including any corporations, limited liability companies, partnerships or trusts, and transactions by these entities should be treated for the purposes of this Policy and applicable securities laws as if they were for the individual's own account. The Company may determine that this Policy applies to additional persons with access to material nonpublic information, such as contractors or consultants. Officers, directors and employees, together with any other person designated as being subject to this Policy by the General Counsel or his or her designee, are referred to collectively as "***Covered Persons***."

Every Covered Person must review this Policy. Questions regarding the Policy should be directed to the Company's General Counsel.

This Policy addresses compliance with applicable U.S. laws. Other laws, including without limitation the laws of the Netherlands and Germany, may also be implicated by trading in the securities of the Company.

II. Statement of Policies Prohibiting Insider Trading

No Covered Person shall purchase, sell, gift or otherwise transfer any type of security while in possession of material nonpublic information relating to the security or the issuer of such security in breach of a duty of trust or confidence, whether the issuer of such security is the Company or any other company. No Covered Person shall purchase, sell, gift or otherwise transfer any security of any other company, including any customer, supplier, business partner or economically-linked company, such as a competitor or peer company, while in possession of material nonpublic information if such information is obtained in connection with the Covered Person's employment by or service to the Company (to the extent there is a reasonable likelihood that such information would be considered important to an investor in making an investment decision in such other company).

These prohibitions do not apply to the following "***permitted transactions***":

- Transactions in the Company's securities directly with the Company;
- Transactions relating to equity incentive awards without any open-market sale of securities (e.g., cash exercises of stock options or the "net settlement" of restricted stock units but not broker-assisted cashless exercise or open-market sales to cover taxes upon the vesting of restricted stock units);
- *401(k) Plans*. To the extent the Company offers its securities as an investment option in the Company's 401(k) plan, the purchase of stock through the Company's 401(k) plan through regular payroll deductions. However, the sale of any such stock, the election to change instructions regarding the level of contributions or to transfer funds into or out of, or a loan with respect to amounts invested in, the stock fund is subject to this Policy;
- *Stock Purchase Plans or Dividend Reinvestment Programs (DRIP)*. To the extent the Company offers its securities as an investment option in an employee stock purchase plan or offers a dividend reinvestment plan, the purchase of stock through the Company's employee stock purchase plan resulting from a periodic contribution pursuant to an election made at the time of enrollment or resulting from the reinvestment of dividends paid on Company stock, respectively. However, the sale of any such stock, the decision to participate in such plan, or changing instructions regarding the level of withholding contributions which are used to purchase such stock, is subject to this Policy;

- Gift transactions for family or estate planning purposes, where securities are gifted to a person or entity subject to this Policy, provided that such gift transactions involving Company securities are subject to pre-clearance;

- "Sell-to-cover" transactions pursuant to a non-discretionary policy adopted by the Company that is intended to facilitate the payment of withholding taxes associated with vesting of equity awards (other than stock options);

- Transactions in the Company's securities made pursuant to a pre-cleared Trading Plan (as defined below) For more information about Rule 10b5-1 trading plans, see Section VI below; or

- Transactions in the Company's securities made pursuant to a pre-cleared "non-Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K.

In addition, Covered Persons shall not directly or indirectly communicate (or "***tip***") material, nonpublic information to anyone outside of the Company (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company other than on a need-to-know basis.

III. Explanation of Insider Trading

"***Securities***" includes stocks, bonds, notes, debentures, options, warrants, and other convertible securities, as well as derivative instruments.

"***Purchase***" and "***sale***" are defined broadly under the federal securities law. "*Purchase*" includes not only the actual purchase of a security, but any contract to purchase or otherwise acquire a security. "*Sale*" includes not only the actual sale of a security, but any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-stock transactions, conversions, the exercise of stock options, transfers, and acquisitions and exercises of warrants or puts, calls, pledging and margin loans, or other derivative securities.

The laws and regulations concerning insider trading are complex, and Covered Persons are encouraged to seek guidance from the General Counsel prior to considering a transaction in Company securities.

A. What Facts Are Material?

Information is considered "material" if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell, or hold a security, or if the information is likely to have a significant effect on the market price of the security. Material information can be positive or negative and can relate to virtually any aspect of a company's business or to any type of security, debt or equity. Also, information that something is likely to happen in the future—or even just that it may happen—could be deemed material.

Examples of material information may include (but are not limited to) information about financial information, including corporate earnings or earnings forecasts; possible mergers,

acquisitions, tender offers, joint ventures, dispositions or changes in assets; major new products or product developments; important business developments such as trial results; developments regarding strategic collaborations or the status of regulatory submissions; major contract awards or cancellations; incidents involving cybersecurity, data protection or personally identifiable information; developments regarding the Company's intellectual property portfolio; management or control changes; changes in the outside auditor or notification by the auditor that the Company may no longer rely on an auditor's report; significant borrowing or financing developments including pending public sales or offerings of debt or equity securities; defaults on borrowings; bankruptcies; and significant litigation or regulatory actions. Moreover, material information does not have to be related to a company's business. For example, the contents of a forthcoming newspaper column that is expected to affect the market price of a security can be material.

A good rule of thumb: When in doubt, do not trade.

B. What Is Nonpublic?

Information is "nonpublic" if it is not available to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors in a Regulation FD-compliant method, such as through a press release, a filing with the US Securities and Exchange Commission (the "***SEC***"), or a Regulation FD-compliant conference call. The General Counsel shall have sole discretion to decide whether information is public for purposes of this Policy.

The circulation of rumors, even if accurate and reported in the media, does not constitute public dissemination. In addition, even after a public announcement, a reasonable period of time may need to lapse in order for the market to react to the information. Generally, the passage of one (1) full trading day following release of the information to the public, is a reasonable waiting period before such information is deemed to be public. For purposes of this Policy, a "trading day" is a day on which U.S. national stock exchanges are open for trading. If, for example, the Company were to make an announcement on a Monday prior to 9:30 a.m. Eastern time, the information would be deemed public after the close of trading on Monday. If an announcement were made on a Monday after 9:30 a.m. Eastern time, the information would be deemed public after the close of trading on Tuesday.

IV. Statement of Procedures to Prevent Insider Trading

The following procedures have been established, and will be maintained and enforced, by the Company to prevent insider trading. Every Covered Person is required to follow these procedures.

A. Pre-Clearance of Transactions by Officers, Directors and Certain Employees

To provide assistance in preventing inadvertent violations of applicable securities laws and to avoid the appearance of impropriety in connection with the purchase, sale, gift or other transfer of the Company's securities, **all transactions in the Company's securities (including without limitation, acquisitions and dispositions of Company stock, gifts, the exercise of stock options and the sale of Company stock issued upon exercise of stock options) by officers, directors and such other employees as are designated from time to time by the Board of Managing**

Directors (the "*Management Board*"), the Chief Executive Officer or the Chief Financial Officer as being subject to this pre-clearance process (with their controlled entities and household members) (each, a "*Pre-Clearance Person*") must be pre-cleared by the General Counsel. For the avoidance of doubt, any designation by the Management Board of the employees who are subject to pre-clearance may be updated from time to time by the General Counsel or the Chief Financial Officer.

A request for pre-clearance must be in writing (including without limitation by e-mail), should be made at least two business days in advance of the proposed transaction and should include the identity of the Pre-Clearance Person, the type of proposed transaction (for example, an open market purchase, a privately negotiated sale, a gift, an option exercise, etc.), the proposed date of the transaction and the number of shares, options or other securities to be involved. In addition, unless otherwise determined by the General Counsel, the Pre-Clearance Person must execute a certification (in the form approved by the General Counsel) that he, she or it is not aware of material, nonpublic information about the Company. The General Counsel shall have sole discretion to decide whether to pre-clear any contemplated transaction, provided that the Chief Financial Officer shall have sole discretion to decide whether to pre-clear transactions by the General Counsel or persons or entities subject to this Policy as a result of their relationship with the General Counsel. All transactions that are pre-cleared must be effected within five (5) business days of receipt of the pre-clearance unless a specific exception has been granted by the General Counsel (or the Chief Financial Officer, in the case of the General Counsel or persons or entities subject to this Policy as a result of their relationship with the General Counsel). A pre-cleared transaction (or any portion of a pre-cleared transaction) that has not been effected during the five business day period must be pre-cleared again prior to execution. Notwithstanding receipt of pre-clearance, if the Pre-Clearance Person becomes aware of material, nonpublic information or becomes subject to a black-out period before the transaction is effected, the transaction may not be completed.

Pre-clearance does not relieve anyone of his or her responsibility under SEC rules and should not be understood to represent legal advice by the Company that a proposed transaction complies with SEC rules or applicable law. None of the Company, the General Counsel, or the Company's other employees will have liability for any delay in reviewing, or refusal of, a request for pre-clearance.

B. Black-out Periods

No officer, director or other employee designated from time to time by the General Counsel or the Chief Financial Officer as being subject to quarterly black-out periods (with their controlled entities and household members) (each a "***Black-out Restricted Person***") shall purchase, sell, gift or otherwise transfer any security of the Company during the period beginning at the time when U.S. national stock exchanges are open for trading (9:30 a.m. Eastern time) on the 10th calendar day in the month following the end of any fiscal quarter of the Company and ending upon completion of one (1) full trading day after the public release of earnings data for such fiscal quarter except as otherwise permitted in Section II. For example, if the Company's fourth fiscal quarter ends on December 31, the corresponding black-out period would begin at 9:30 a.m. Eastern time, on January 10 and end at the close of trading (generally, 4:01 p.m., Eastern time) on the first full trading day after the public release of earnings data for such quarter ended December 31. For

the avoidance of doubt, any designation by the Management Board of the employees who are subject to quarterly black-out periods may be updated from time to time by the Chief Financial Officer or the General Counsel.

Exceptions to the black-out period policy may be approved only by the General Counsel (or, in the case of an exception for the General Counsel or persons or entities subject to this Policy as a result of their relationship with the General Counsel, the Chief Financial Officer). Such exceptions can only be granted if the requesting Black-out Restricted Person is not in possession of material non-public information about the Company and is not otherwise prohibited from trading pursuant to this Policy. Such exceptions are granted extremely infrequently and only in extraordinary circumstances.

From time to time, the Company, through the Management Board, the Company's Disclosure Committee or the General Counsel, may recommend that officers, directors, employees or others suspend trading in the Company's securities because of developments that have not yet been disclosed to the public. Subject to the exceptions noted above, all those affected should not trade in the Company's securities while the suspension is in effect and should not disclose to others that the Company has suspended trading. If the Company declares such an ad hoc black-out period to which you are subject, you will be notified when such black-out begins and when it ends.

C. Post-Termination Transactions

With the exception of the pre-clearance requirement, this Policy continues to apply to transactions in the Company's securities even after termination of service to the Company. If you are in possession of material nonpublic information when your service terminates, the restrictions set forth in this Section IV continue to apply until that information has become public or is no longer material.

V. Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. Therefore, Covered Persons shall comply with the following policies with respect to certain transactions in the Company's securities:

A. Short Sales

Short sales of the Company's securities evidence an expectation on the part of the seller that the securities will decline in value, and therefore signal to the market that the seller has no confidence in the Company or its short-term prospects. Short sales may reduce the seller's incentive to improve the Company's performance. In addition, Section 16(c) of the Exchange Act prohibits Section 16 reporting persons (i.e., directors, officers, and the Company's 10% stockholders) from making short sales of the Company's equity securities. **For these reasons, short sales of the Company's securities are prohibited by this Policy.**

B. Options

A transaction in options is, in effect, a bet on the short-term movement of the Company's stock and therefore creates the appearance that a Covered Person is trading based on material, nonpublic information. Transactions in options, whether traded on an exchange on any other organized market or on an over the counter market, also may focus a Covered Person's attention on short-term performance at the expense of the Company's long-term objectives. **Accordingly, transactions in puts, calls or other derivative securities involving the Company's equity securities, on an exchange, on any other organized market or on an over the counter market, are prohibited by this Policy**.

C. Hedging Transactions

Purchasing financial instruments, such as prepaid variable forward contracts, equity swaps, collars, and exchange funds, or otherwise engaging in transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of the Company's equity securities, may cause a Covered Person to no longer have the same objectives as the Company's other shareholders. **Therefore, all such transactions involving the Company's equity securities, whether such securities were granted as compensation or are otherwise held, directly or indirectly, are prohibited by this Policy**.

D. Purchases of the Company's Securities on Margin; Pledging the Company's Securities to Secure Margin or Other Loans

Purchasing on margin means borrowing from a brokerage firm, bank, or other entity in order to purchase the Company's securities (other than in connection with a cashless exercise of stock options under the Company's equity plans). **Margin purchases of the Company's securities are prohibited by this Policy. Pledging the Company's securities as collateral to secure loans is also prohibited.** This prohibition means, among other things, that you cannot hold the Company's securities in a "margin account" (which would allow you to borrow against your holdings to buy securities). Notwithstanding the foregoing, under certain circumstances an exception may be granted for a Covered Person to pledge Company securities as collateral for a loan (not including margin debt) where the Covered Person clearly demonstrates the financial capacity to repay the loan without resorting to the pledged securities. Any Covered Person that wishes to do so must submit a pre-clearance request to the General Counsel at least two (2) weeks prior to the proposed execution of documents evidencing the proposed pledge. The General Counsel shall have absolute discretion over approving or rejecting such proposed pledge and may impose additional requirements in connection with granting the pre-clearance request, including a requirement that the proposed pledgee expressly agrees to accept the terms of this Policy with respect to such pledged Company securities to the reasonable satisfaction of the General Counsel. The Company shall assume no liability for the consequences of any transaction made pursuant to such request.

E. Standing Orders

A standing order placed with a broker to sell or purchase Company securities at a specified price leaves the security-holder with no control over the timing of the transaction. A transaction pursuant to a standing order, which does not meet the standards of a Trading Plan (as defined below) approved in compliance with this Policy, executed by the broker when the Covered Person

is aware of material nonpublic information about the Company, may result in unlawful insider trading. Other than in connection with a Trading Plan under this Policy, entry into or fulfillment of a standing order is prohibited whenever a Covered Person is in possession of material nonpublic information about the Company (including during a quarterly black-out period for Black-out Restricted Persons or ad hoc black-out period for those insiders subject to such procedures). All standing orders must be of limited duration, cancelable, and in the case of a Black-out Restricted Person or person subject to an ad hoc black-out period, must be immediately canceled upon commencement of quarterly black-out or ad hoc black-out period, as applicable.

F. Partnership Distributions

Nothing in this Policy is intended to limit the ability of a venture capital partnership or other similar entity with which a director is affiliated to distribute Company securities to its partners, members, or other similar persons. It is the responsibility of each affected director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

VI. Rule 10b5-1 Trading Plans

The restrictions in this Policy, except for provisions set forth in Section V, do not apply to transactions under a trading plan (a "***Trading Plan***") that satisfies either:

- the conditions of Rule 10b5-1; or
- the elements of a non-Rule 10b5-1 trading arrangement as defined in Item 408(c) of Regulation S-K; and
- the General Counsel has pre-approved.

The General Counsel may impose such other conditions on the implementation and operation of a Trading Plan as the General Counsel deems necessary or advisable.

An individual may only modify a Trading Plan outside of a black-out period and, in any event, when the individual does not possess material nonpublic information. Modifications to and early terminations of a Trading Plan are subject to pre-approval by the General Counsel.

The Company also reserves the right from time to time to suspend, discontinue, or otherwise prohibit transactions under a Trading Plan if the General Counsel or the Board of Supervisory Directors, in its or their discretion, determines that such suspension, discontinuation, or other prohibition is in the best interests of the Company.

Compliance of a Trading Plan with the terms of Rule 10b5-1 and the execution of transactions pursuant to the Trading Plan are the sole responsibility of the person initiating the Trading Plan, and none of the Company, the General Counsel, or the Company's other employees assumes any liability for any delay in reviewing and/or refusing to approve a Trading Plan submitted for approval, nor the legality or consequences relating to a person entering into, informing the Company of, or trading under, a Trading Plan.

VII. Policy Administration

The Company's General Counsel shall be responsible for the administration of this Policy. The General Counsel shall have the authority to interpret and update this Policy and all related policies and procedures. In particular, such interpretations and updates of this Policy, as authorized by the General Counsel, may include amendments to or departures from the terms of this Policy, to the extent consistent with the general purpose of this Policy and applicable securities laws. Actions taken by the Company, the General Counsel, or any other Company personnel do not constitute legal advice, nor do they insulate you from the consequences of noncompliance with this Policy. In the absence of the General Counsel, responsibility for administering this Policy will rest with the Chief Financial Officer or such other employee as may be designated by the General Counsel.

The Company's Board of Supervisory Directors will approve any waiver of the terms of this Policy for supervisory directors or officers.

VIII. Certification of Compliance

All Covered Persons may be asked periodically to certify their compliance with the terms and provisions of this Policy.

Exhibit 21.1

Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
atai Holdco, Inc.	Delaware
atai Life Sciences US, Inc.	Delaware
atai Life Sciences AG	Germany
atai Life Sciences UK Ltd	England and Wales
atai Therapeutics, Inc. (f.k.a. Viridia Life Sciences, Inc.)	Delaware
atai Therapeutics Holdings, Inc.	Delaware
EmpathBio, Inc.	Delaware
GABA Therapeutics, Inc.	Delaware
IntelGenx Corp.	Canada
Perception Neuroscience Holdings, Inc.	Delaware
PsyProtix, Inc.*	Delaware
Recognify Life Sciences, Inc.	Delaware

*Merged into atai Therapeutics, Inc. on December 31, 2024

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-265970 on Form S-3 and Registration Statement No. 333-257482 on Form S-8 of our report dated March 17, 2025, relating to the financial statements of ATAI Life Sciences N.V. appearing in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey
March 17, 2025

Exhibit 31.1

CERTIFICATION

I, Srinivas Rao, certify that:

1. I have reviewed this Annual Report on Form 10-K of ATAI Life Sciences N.V.;

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2025

By: /s/ Srinivas Rao
Srinivas Rao
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Anne Johnson, certify that:

1. I have reviewed this Annual Report on Form 10-K of ATAI Life Sciences N.V.;

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2025

By: /s/ Anne Johnson

Anne Johnson
Chief Financial Officer
(*Principal Financial Officer)*

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ATAI Life Sciences N.V. (the "Company") for the fiscal year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 17, 2025

By: /s/ Srinivas Rao
Srinivas Rao
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ATAI Life Sciences N.V. (the "Company") for the fiscal year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 17, 2025

By: /s/ Anne Johnson
Anne Johnson
Chief Financial Officer
(Principal Financial Officer)