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, 2023

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, 2023, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $203.3 million. Solely for purposes of this disclosure, common shares held by executive officers, directors and certain shareholder of the Registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 1, 2024, the registrant had 166,026,396 common shares, par value €0.10 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement relating to its 2024 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, 2023, are incorporated herein by reference in Part III where indicated.

ATAI Life Sciences N.V.

FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (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, 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.

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, 2023.

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.life. 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. 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;
- 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 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, such as the COVID-19 pandemic, 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.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. We were founded in 2018 in response to the significant unmet need and lack of innovation in the mental health treatment landscape. We are dedicated to efficiently developing and investing in innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. By pooling resources and best practices, we aim to responsibly accelerate the development of new medicines to achieve clinically meaningful and sustained behavioral change in mental health patients.

We have a bold and ambitious vision: to heal mental health disorders so that everyone, everywhere can live a more fulfilled life.

Mental health disorders such as depression, substance use disorder, and anxiety, which are among our initial focus indications, are highly prevalent and estimated to affect more than one billion people globally. In addition, the total costs of mental health disorders are significant and expected to increase substantially. 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 the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors, or SSRIs, and serotonin-norepinephrine reuptake inhibitors, or SNRIs, are well established and effective for certain patients, a significant percentage of patients either respond inadequately or relapse, translating to a significant unmet patient need.

Our Model and Strategy

We have a team of experienced drug discoverers, developers and innovators working to heal mental health disorders. At atai we have a robust portfolio of drug development programs that have either been acquired through strategic investments or created de novo through our drug development platform. To continue to grow our business and to aid in the development of our various programs, we intend to continue to incubate, acquire and invest in companies that share our goal of advancing transformative treatments for patients that suffer from mental health disorders.

We believe in a modular approach to capturing value as we advance therapies through commercialization. While our primary goal is to pursue commercialization of products independently, we also intend to continue opportunistically establishing collaborations and/or divest atai companies entirely based on several factors, including, without limitation, the strategic rationale and financial return potential. The model is designed to maximize the value of each drug that we successfully develop and generate returns for shareholders through these value-capturing strategies.

Our Programs

We have built a diversified pipeline of drug and discovery development programs, including psychedelic and nonpsychedelic compounds. Psychedelics are emerging as novel breakthrough 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 potential efficacy and safety profile of psychedelics, which may have potential therapeutic benefits, such as a rapid onset of effect and sustained efficacy after a short-course of administration. We believe 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, indication and mechanism of action, which we believe will improve the commercial potential and risk profile of our pipeline in the aggregate. We also prioritize the development of compounds and compound classes that have shown potential for efficacy and safety in prior clinical trials or observational studies.

Our Strategic Investments

COMPASS Pathways plc (“COMPASS”) is developing its investigational COMP360 psilocybin therapy, which comprises administration of COMP360 with psychological support from specially trained therapists, with an initial focus on treatment-resistant depression (“TRD”). COMPASS is currently conducting a Phase 3 pivotal program composed of two pivotal trials, each of which will have a long-term follow-up component. Top-line pivotal data for the first and second trials are expected in the fourth quarter of 2024 and mid-2025, respectively. As of December 31, 2023, we beneficially owned 9,565,774 shares representing a 15.4% equity interest in COMPASS. Certain of our founding investors were also seed investors and/or founders of COMPASS. Our interest in the product candidates of COMPASS is limited to the potential appreciation of our equity interest.

Beckley Psytech Psytech Limited ("Beckley Psytech") is developing its investigational compounds, BPL-003 5 Methoxy N,N-dimethyltryptamine benzoate ("5-MEO-DMT") for treatment of TRD and Alcohol Use Disorder ("AUD") and ELE-101 psilocin therapy for the treatment of Major Depressive Disorder ("MDD"). Beckley Psytech is conducting a Phase 2b controlled study of BPL-003 in

patients with TRD, with an anticipated readout in second half of 2024. Initial results from the BPL-003 open-label Phase 2a in TRD were announced in March 2024. Initial results from the BPL-003 open-label Phase 2a study in AUD are anticipated mid-2024. Initial results from the current ELE-01 Phase 1/2a study are anticipated in the first half of 2024. In January 2024, we invested in Beckley Psytech resulting in a 35.5% ownership stake and 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. atai and Beckley Psytech also agreed to collaborate on digital therapeutics, commercial and market access activities in preparation for future potential commercialization. Our interest in the product candidates of Beckley Psytech is limited to the potential appreciation of our equity interest.

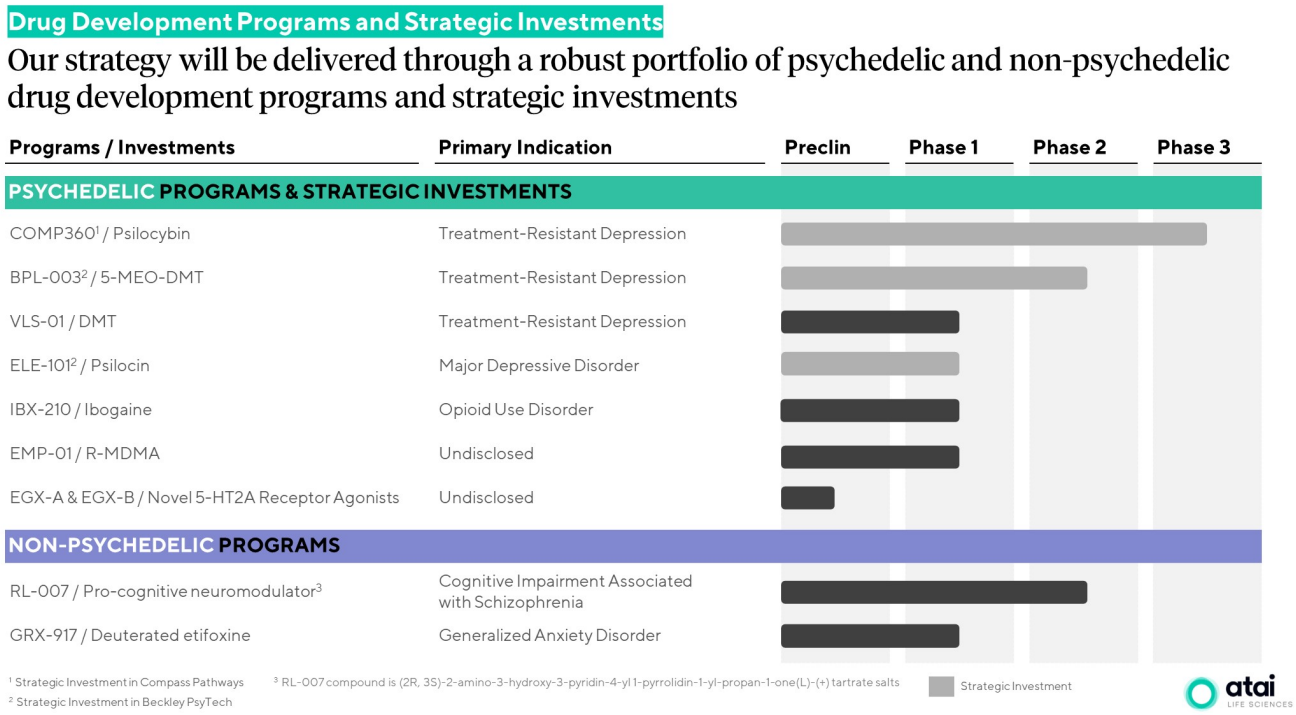
Our Enabling Technologies and Drug Discovery Platforms

We are developing enabling technologies that have the potential to support the programs in our pipeline. We currently have enabling technologies housed at our atai companies, as well as IntelGenx Technologies, a strategic investment of ours. While many of these technologies remain in early stage development, in October 2023, we announced the completion of a Phase 1 study in healthy participants, in which pharmacokinetic ("PK") and pharmacodynamic ("PD") data confirmed systemic delivery of VLS-01 via, a proprietary oral transmucosal film ("OTF") formulation of N,N-dimethyltryptamine ("DMT"), via the oral, transmucosal route at levels comparable to those achieved with 30 mg intravenous ("IV") administration of DMT.

In addition, we also conduct early-stage drug discovery through our discovery platform. Expanding intellectual property has been essential to our strategy since inception, with key investments made to unlock NCEs. We have made substantial progress in our drug discovery efforts to date, synthesizing and screening approximately 700 compounds and identifying novel scaffolds that display potential in targeting mental health disorders.

Our Pipeline

Our pipeline currently consists of therapeutic candidates across multiple neuropsychiatric indications including depression, anxiety, opioid use disorders ("OUD"), and cognitive impairment associated with schizophrenia ("CIAS"). The table below summarizes the status of our product candidate portfolio as of the date of this Form 10-K.



The following details our key psychedelic programs and strategic investments, as well as our non-psychedelic programs, including related

prior evidence in humans based on completed and/or on-going clinical trials or studies, recent advancements and upcoming milestones, as applicable:

Psychedelic Programs & Strategic Investments

COMP360 (via Strategic Investment in COMPASS)

- **Product Candidate Concept**: COMP360 is a proprietary psilocybin formulation that includes pharmaceutical-grade polymorphic crystalline psilocybin, optimized for stability and purity. By activating a distinct set of receptors in brain areas critical to mood and cognition, psilocybin acts to induce a range of downstream effects that may have important, sustained effects on brain function. In this way, evidence of the molecular, cellular, and systemic effects of psilocybin in the CNS supports the potential for psilocybin in the treatment of mental health conditions. At the molecular level, psilocybin is rapidly metabolized to its active metabolite psilocin, which is a partial agonist at several 5-hydroxytryptamine (serotonin), or 5-HT, receptors, also known as serotonin receptors, including 5-HT2A, 2C, and 1A receptors. This means that psilocin binds to and activates these receptors, all of which are expressed in neurons in different areas of the CNS. In particular, many of the prominent acute effects of psilocybin, such as changes in emotion and cognition, are thought to be mediated by 5-HT2A receptor stimulation, an interpretation that is supported by the fact that blocking the 5-HT2A receptor prevents the psychedelic effects of psilocybin in humans. COMP360 is currently being evaluated in a pivotal program in patients with TRD with additional Phase 2 studies being conducted in post-traumatic stress disorder and anorexia.

- **Disease Overview**: Major depressive disorder, or MDD, is characterized by persistent depressed mood and loss of interest or pleasure in most daily activities of at least two weeks' duration. These symptoms are often accompanied by fatigue, difficulty concentrating, psychomotor impairments and suicidal ideation, among others. Depression is one of the most prevalent psychiatric disorders and a leading cause of disability worldwide, affecting an estimated 300 million people globally. Treatment resistant depression, referred to as TRD, is a subtype of MDD. TRD is a severe form of MDD, comprising patients who do not respond adequately to two or more pharmacological treatments. Approximately one third of patients with MDD are diagnosed with TRD.

  TRD is estimated to affect approximately 100 million people globally. People with TRD are often unable to perform daily tasks, are less productive at work and have high rates of unemployment. People with TRD are also more likely to receive disability or welfare benefits and are reported to have a higher frequency of co-occurring conditions, including hypertension, anemia, and diabetes, compared to people with MDD who are not treatment resistant. In addition, direct medical costs for people with TRD are estimated to be two to three times higher than for people with MDD who are not treatment resistant, with an average of twice the number of inpatient visits and hospital stays that are over one-third longer. It has been found that the proportion of people with TRD who have attempted suicide may be as high as 30%, approximately a seven-fold increase compared to people with MDD who are not treatment resistant.

  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.

- **Prior Clinical Evidence:**

  Phase 1 Healthy Volunteer Study

  In its initial Phase 1 healthy volunteer trial, COMPASS observed that COMP360 was generally well-tolerated and supported continued progression of Phase 2b studies. The trial also showed the feasibility of simultaneous administration of COMP360 to up to six people in the same facility, with 1:1 therapist support. In August 2020, the FDA approved COMPASS's request for a 1:1 model of therapist support.

  Phase 2b Study in patients with TRD

  COMPASS evaluated COMP360 in conjunction with psychological support in a Phase 2b trial that concluded in July 2021 and reported its positive Phase 2b data for its proprietary psilocybin COMP360 for TRD in November 2021. The 233-patient trial met its primary endpoint, showing a 6.6-point reduction on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to 3 weeks when comparing the 25mg dose to the 1mg dose. COMP360 also showed both rapid response and durability of efficacy and was generally well tolerated.

- **Recent Advancements**: At the beginning of 2023, a Phase 3 program evaluating COMP360 psilocybin treatment in TRD was initiated. The Phase 3 program is composed of two pivotal trials, each with a long-term follow-up component. The pivotal program design is as follows: Pivotal trial 1 (COMP005) (n=255): a single dose (25mg) monotherapy compared with placebo. This trial is designed to replicate the treatment response seen in our Phase 2b trial (n=233). Top-line data is expected in the fourth quarter of 2024. Pivotal trial 2 (COMP006) (n= 568): a fixed repeat dose monotherapy using three dose arms: 25mg, 10mg and 1mg. This trial is designed to investigate whether a second dose can increase treatment responders and whether a second dose can improve responses observed in our Phase 2b trial and to explore the potential for a meaningful treatment response from repeat administration of COMP360 10mg. Top-line data is expected by mid-2025. The primary endpoint in both pivotal trials is the change from baseline in the MADRS (Montgomery-Åsberg Depression Rating Scale) total score at week 6.

BPL-003 (via Strategic Investment in Beckley Psytech)

- **Product Candidate Concept**: BPL-003 is a dry powder, intranasal formulation of the benzoate salt form of 5-MeO-DMT, a psychoactive indolealkylamine derivative of tryptamine. 5-MeO-DMT 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 activity at 5-HT receptors is considered to be the mechanism for its psychoactive effects and, although it has affinity for a broad range of 5-HT receptors, its actions at serotonin 1A (5-HT1A) and serotonin 2A (5-HT2A) receptors are considered to be the most important for the majority of its reported activities. The lead indication for BPL-003 is TRD, with on-going Phase 2a and 2b studies. There is also an on-going Phase 2a study in AUD.
- **Disease Overview**: See "— COMP360 (via Strategic Investment in COMPASS) – Disease Overview" for an overview of MDD and TRD
- **Prior Clinical Evidence**:

  Phase 1 Study of BPL-003 in Healthy Volunteers

  A two-part, phase 1, single ascending dose study was conducted to evaluate the safety, tolerability and PK profile of BPL-003 in healthy subjects. BPL-003 was safe and well-tolerated in the study, with a PK profile that was approximately dose linear. In this study assessments were made of PD endpoints that are thought to be predictive of efficacy outcomes in TRD subjects. Literature data indicate that the 30-item Mystical Experience Questionnaire (MEQ-30) data may be used as a surrogate marker of potential future psychiatric efficacy, and so was the key PD outcome measure conducted. A score of ≥3 was defined to be the threshold to elicit a significant experience. A score of ≥3 in all four subdomains of the MEQ-30 was defined as a complete Mystical Experience. The mean subject MEQ-30 scores generally increased with BPL-003 dose, with levels ≥3 being observed at doses of 6 mg and above in at least one sub-domain or total MEQ-30 score. The highest MEQ-30 scores were attained with 12 mg BPL-003, and three of five subjects (60%) achieved a complete Mystical Experience at 10 mg and 12 mg doses.
- **Recent Advancements:** BPL-003 is currently being investigated in an on-going Phase 2a open-label study and an on-going Phase 2b double-blind, randomized, controlled study in people living with TRD. In addition, the company is also conducting an open-label Phase 2a study in patients with AUD.

  In March 2024, the company 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 Montgomery–Åsberg Depression Rating Scale (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 4and 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.

  A Part 2 extension of this Phase 2a open-label study is now enrolling patients with TRD who are on stable doses of oral antidepressants to assess the safety and efficacy of BPL-003 co-administration.

A randomized, quadruple-masked, controlled Phase 2b study of BPL-003 is currently underway. 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 225 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. Top-line results are expected in H2 2024.

Lastly, BPL-003 is also being investigated in the open-label Phase 2a study in AUD, with initial data expected mid-2024.

VLS-01 (N,N-Dimethyltryptamine; ("DMT") for TRD

- **Product Candidate Concept:** VLS-01 is an oral transmucosal film ("OTF") formulation of DMT. Pharmacologically, DMT is a partial agonist of the 5-HT-1A/2A/2C receptors, developed to induce a short duration of psychedelic effect of approximately 30 to 45 minutes, with a serum half-life estimated at less than 10 minutes. Intravenous ("IV") DMT administration results in rapid-acting antidepressant effects in patients with major depressive disorder. VLS-01's OTF may eliminate the need for IV infusion.
- **Disease Overview:** See "— COMP360 (via Strategic Investment in COMPASS) – Disease Overview" for an overview of MDD and TRD.
- **Prior Evidence – Non-Clinical and Clinical Data:**

  VLS-01 Non-Clinical

  Neural plasticity is considered to be a critical mechanism by which serotonergic psychedelics exert antidepressant effects. DMT acts as a partial agonist of the 5-HT 1A/2A/2C receptors, primarily in cortical neurons and the limbic system, where it is believed to increase neuroplasticity and decrease functional connectivity. In vitro and in vivo assays for neuritogenesis and synaptogenesis in the prefrontal cortex of adult rats demonstrated DMT's potential to significantly increase dendritic arbor complexity along with functionality (assessed by ex-vivo slice recordings of excitatory postsynaptic currents ("EPSCs"), suggesting the potential to restore prefrontal cortex deficits observed in the pathophysiology of depression.

  In a series of behavioral experiments conducted in male rats, a single intraperitoneal injection of 10 mg/kg DMT, a hallucinogenic dose based on rodent drug discrimination data, demonstrated an antidepressant-like effect in the forced swim test, as indicated by a significant reduction in immobility and increase in swimming.

  DMT has limited oral bioavailability, and current clinical studies conducted by third parties typically involve either IV or inhaled routes of administration. Given the challenges—both commercial and safety—with these routes, we are developing VLS-01 as an OTF formulation, which is expected to provide a more convenient and acceptable route of administration. Our improved proprietary formulation has demonstrated good mucosal penetration of DMT when tested in vitro in a standard model involving pig mucosal tissue.

  Phase 2a Study of IV DMT fumarate in Major Depressive Disorder

  The third-party Phase 2a study investigated the safety and efficacy of DMT fumarate with supportive therapy compared to placebo with supportive therapy, in 34 patients with moderate/severe MDD. Patients were administered a short IV infusion of 21.5mg of DMT fumarate, resulting in a 20 to 30-minute psychedelic experience. The study met the primary and key secondary endpoints, demonstrating a placebo-adjusted reduction of -10.8 (p=0.002) and -7.4 (p=0.02) in MADRS scores at one- and two-weeks post-dose, respectively. DMT fumarate was well tolerated with no drug-related serious adverse events reported, including no reports of suicidal ideation or behavior. There were no clinically significant safety concerns in any treatment group, including with vital signs, electrocardiogram ("ECG") or clinical laboratory findings.

  We believe this study provides strong proof of concept data for DMT as a potential treatment for depression and supports the development of the OTF formulation of DMT, VLS-01, which may simplify in-clinic administration relative to an IV formulation.
- **Recent Advancements:** In March 2024, we dosed the first participant in the Phase 1b study of VLS-01. The study is expected to explore doses up to 240 mg with an optimized OTF that incorporates taste masking, an intrinsic backing layer, and enhancements designed to increase permeability with goals of further improving the participant experience and PK. Top-line results are expected in the second half of 2024.

ELE-101 (via Strategic Investment in Beckley Psytech)

- **Product Candidate Concept:** ELE-101 is 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**: See "— COMP360 (via Strategic Investment in COMPASS) – Disease Overview" for an overview of MDD and TRD.
- **Prior Evidence:** See "— COMP360 (via Strategic Investment in COMPASS) – Prior Clinical Evidence".
- **Recent Advancements:** ELE-101 is currently being studied in a two-part Phase 1/2a study. The Phase 1 portion (Part 1) of the study is a randomized, double-blind, placebo-controlled study to assess safety, tolerability, PK and PD of single ascending IV doses of ELE-101 in healthy volunteers. The Phase 2 portion of the study will evaluate a range of PD effects of a single IV dose of ELE-101 in patients with MDD. Initial results from the Phase 1/2a study are anticipated in the first half of 2024.

IBX-210*:* (ibogaine) for Opioid Use Disorder ("OUD")

- **Product Candidate Concept:** IBX-210is an intravenous formulation of ibogaine, a naturally occurring oneirogenic and psychedelic compound isolated from a West African shrub with cholinergic, glutamatergic and monoaminergic receptor modulatory activity which we are developing for the treatment of OUD. The company was previously developing DMX-1002, an oral formulation of ibogaine.
- **Disease Overview: Substance abuse disorders (**"SUD")s are highly prevalent disorders characterized by an inability to control the use of a legal or illegal drug, medication or other psychoactive compound. SUDs typically occur following prolonged, repeated use of a substance at high doses and/or high frequencies and can lead to significant health and social consequences. According to the National Survey on Drug Use and Health, 19.7 million adults in the United States suffered from an SUD in 2017.

  We are initially focused on OUD, a form of SUD characterized by uncontrolled and persistent self-administration of opioids, resulting in significant impairment, distress, and mortality. In 2017, an estimated 2.1 million people in the United States had an OUD, and 47,600 people died from an opioid drug overdose. OUD's societal effects are extremely far-reaching as the condition burdens multiple stakeholders. A retrospective secondary analysis using 2018 data from the National Survey on Drug Use and Health and the CDC WONDER Database attributed a $787 billion societal cost to OUD in the United States alone. The most common treatments for OUD are directed at achieving abstinence and include psychological and social interventions.

  There are limited pharmacological agents available to treat OUD, with the current options divided into two classes: (i) synthetic opioid receptor full or partial agonists, such as methadone and buprenorphine, respectively, and (ii) opioid antagonists, such as naltrexone and naloxone. These therapies suffer from a number of limitations, including high relapse rates, inconvenient treatment regimens, difficult access and an inability to maintain abstinence after medically assisted withdrawal.
- **Prior Clinical Evidence:**

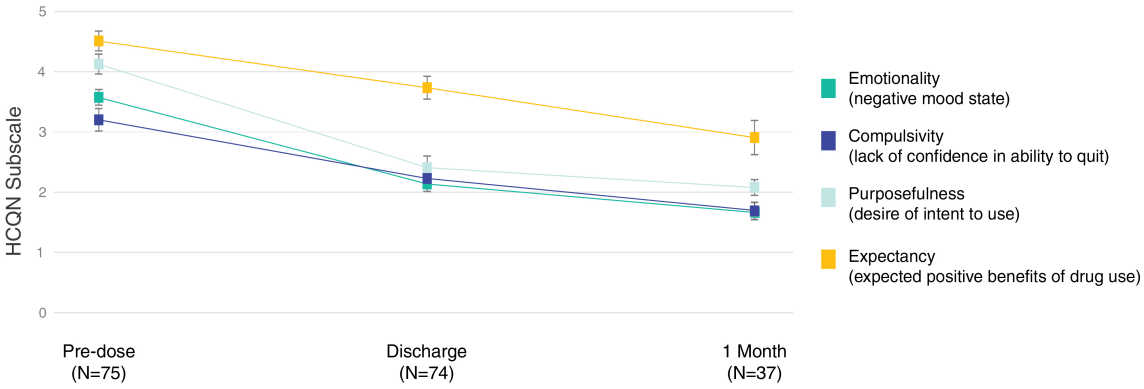
  2018 Publication of Investigator Initiated Case Studies of an Oral Ibogaine Formulation (Mash et. al.)

  A single dose of another formulation of ibogaine has been shown in several case series to be an effective treatment for acute opioid withdrawal, from both the physiological and psychological perspectives. A 2018 publication authored by the founder of DemeRx IB describes the results of clinical use of ibogaine to treat SUD in over 180 patients. In this clinical study, treatment of 75 opioid-dependent and 81 cocaine-dependent patients with single doses of 8 mg/kg to 12 mg/kg ibogaine led to significant and durable reductions in ratings of craving at discharge on day 12 and at one-month post-treatment. In addition, both opioid- and cocaine-dependent patients reported improved mood from as early as five days after dosing up to at least one-month follow-up.

  Ibogaine was generally well tolerated when administered in a highly controlled clinical setting. All patients experienced a hallucinatory, dream-like state which typically resolved between six and 12 hours after dosing, though subjective effects were observed up to 24 hours after dosing in some subjects. There were no serious adverse events or deaths that occurred from administration of ibogaine to drug dependent patients in the dose range used in this trial.

As shown below, opioid-dependent patients reported significant decreases in drug craving as measured by all Heroin Craving Questionnaire-29 subscales at discharge and at one-month follow-up. Similarly, assessments of mood (The Beck Depression Inventory ("BDI"), The Profile of Mood States, or POMS, depression subscale, Symptom Checklist-90 depression subscale) revealed significant reductions in depression, as well as improvement in mood scores from baseline to post-dose and at one-month follow-up ($p<0.01$ for all).

PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY[1])



Note: HCQN = Heroin Craving Questionnaire, PK = Pharmacokinetics.
1. Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abusers Between Dependence and Abstinence: Clinical Observations and Treatment Outcomes" (2018)

2014 Publication of a Double Blind, Placebo Controlled Study of Ibogaine in Cocaine Use Disorder (Prior et. al.)

A double blind, placebo controlled study was conducted with 20 patients (N=20), split in 2 groups: the ibogaine group received a single dose of 1800 mg of encapsulated ibogaine extract and the placebo group received a single capsule of sugar powder. All patients were followed for a 24-week period, with biweekly visits to a psychiatric professional, in which a urine sample was collected in order to detect cocaine use. Data analyzes was performed using ANOVA for repeated measures for comparison of data between groups and between members of the same group. Urine samples were compared (positive results) using measure ANOVA statistical tests with the Least Squares Difference for post hoc two group comparisons. Statistical significance was 5% ($P< 0.05$) for all the referred tests.

Phase 1 Study of DMX-1002 (Ibogaine) in Opioid Use Disorder

A phase 1/2a study was initiated to assess safety, tolerability, PK, and potential for clinical activity in health volunteers and patients with OUD. In August 2023, we announced the results from the Phase 1 portion of the study. The single-blinded Phase 1 study assessed the safety, tolerability and PK of single-ascending doses of DMX-1002 in healthy volunteers. Oral doses of 3 mg/kg, 6 mg/kg & 9 mg/kg were evaluated in 20 participants. Results of the Phase 1 trial demonstrated that oral doses of DMX-1002 at 9 mg/kg achieved plasma concentrations in line with those described in previous studies[1,2] in which subjects reported psychedelic experiences and obtained therapeutic benefit in OUD. However, a marked interpatient variability in the PK of both ibogaine and its major metabolite, noribogaine, were noted.

The treatment-related adverse events ("AEs") were similar to those observed in prior trials of DMX-1002, and nearly all (>94%) were rated mild-to-moderate in severity. There were no serious adverse events reported. QT prolongation was observed at all three doses tested, and on one of the two participants who received 9 mg/kg of DMX-1002, QT prolongation reached levels near those seen at the 10 mg/kg dose in the published literature[3] (median change: 95ms). In this participant, a QTcF prolongation of 90-94ms was observed with a QTcF interval of 493-501ms. The patient was asymptomatic, with no cardiac arrythmias, and the QTc change resolved without intervention or sequalae.

1. DC Mash et. al. [1998]; 2. DC Mash et. al. [2018]; 3. T Knuijver et al. [2021]

- **Recent Advancements:** Based on the analysis of the Phase 1 results, atai is exploring IBX-210, a novel IV formulation of ibogaine, that is designed to improve safety, reduce PK variability and lead to a shorter and more predictable time in-clinic that is anticipated to improve scalability and patient access relative to oral ibogaine (DMX-1002). We plan to engage regulatory authorities to assess progressing IBX-210 into an efficacy study in patients with OUD.

EMP-01: R-3,4-methylenedioxy-methamphetamine ("R-MDMA")

- **Product Candidate Concept:** EMP-01 is an oral formulation of an R-MDMA.
- **Recent Advancements:** In January 2024, we announced positive top-line results from the Phase 1 study. EMP-01 was well-tolerated, and treatment-related adverse events (AEs) were all expected and generally dose dependent. There were no study discontinuations, and no serious or severe AEs were observed in the study. The PK profile of EMP-01 was dose-proportional. PD measures included both subjective reports and blood-based biomarkers. Significant, consistent, and dose-dependent changes were seen on several of these exploratory PD measures. EMP-01 administration resulted in a differentiated subjective experience compared to racemic MDMA on standard psychedelic experience questionnaires. Further, dose dependent changes on measures of emotional breakthrough, a phenomenon thought to be a key mediator of the long-term psychological changes associated with psychedelics, were noted in this healthy volunteer population.EMP-01 was well-tolerated in all cohorts. We are currently evaluating next steps for the development of EMP-01.

EGX-A and EGX-B: Novel 5-HT2A Receptor Agonists

- **Product Candidate Concept:** EGX-A and EGX-B are lead candidates from atai's 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 atai's drug discovery effort, novel 5-HT2A receptor agonists were discovered that are non-hallucinogenic based on animal studies. The molecules are being further optimized and studied in animal models to assess therapeutic potential.

Non-Psychedelic Programs

RL-007

- **Product 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. We are initially developing this compound for the treatment of CIAS.
- **Disease Overview:** Schizophrenia is a chronic psychiatric disorder characterized by a heterogeneous combination of symptoms, including psychosis, social withdrawal, flattened affect and cognitive impairment. It is one of the most debilitating mental illnesses known and often requires patients to be under medical care for their entire lives. People living with schizophrenia often experience a reduced life expectancy and quality of life, and are more likely to be homeless, unemployed or living in poverty compared with the general population. It is estimated that schizophrenia affects over 21 million people globally and approximately 2.4 million people in the United States. Approximately 300,000 new cases are diagnosed each year in the United States. Nearly every schizophrenia patient is affected by CIAS, limiting both social and non-social cognitive functions.

  While antipsychotics are most commonly used to treat the psychotic symptoms of schizophrenia, they fail to address the cognitive and negative symptoms of this condition. Moreover, there are no drugs approved for the specific treatment of CIAS.

- **Prior Evidence - Non-Clinical & Clinical Data:**

  Non-Clinical

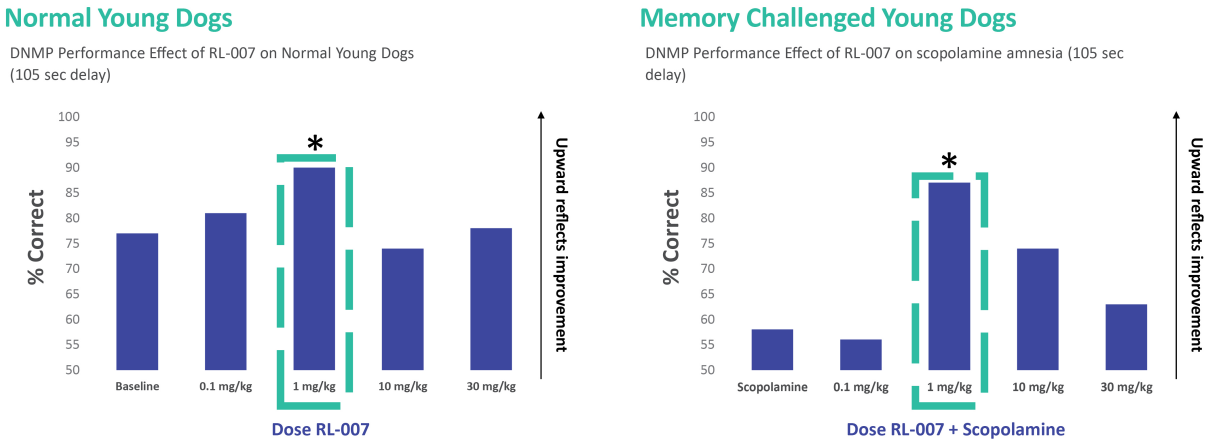
  RL-007 has been shown to be active in a broad range of non-clinical models, consistently exhibiting pro-cognitive, anxiolytic, antinociceptive and anticonvulsant effects.

  Studies with co-delivered antagonists suggest that RL-007 modulates both inhibitory and excitatory neuronal signaling through the γ-aminobutyric acid B (GABAB) and nicotinic α4β2 receptor complexes.

  In contrast to other compounds that are agonists of GABAB receptors, RL-007 does not appear to induce the classic GABA side effects such as sedation (in animal models), suggesting the involvement of additional pharmacological mechanisms.

  Studies in several species have demonstrated that RL-007 can reverse the effects of scopolamine, a muscarinic antagonist that induces temporary cognitive impairment, and can also improve performance in complex memory tasks in aged animals, bringing their performance to a comparable level as young animals. For example, in an in vivo model in normal and

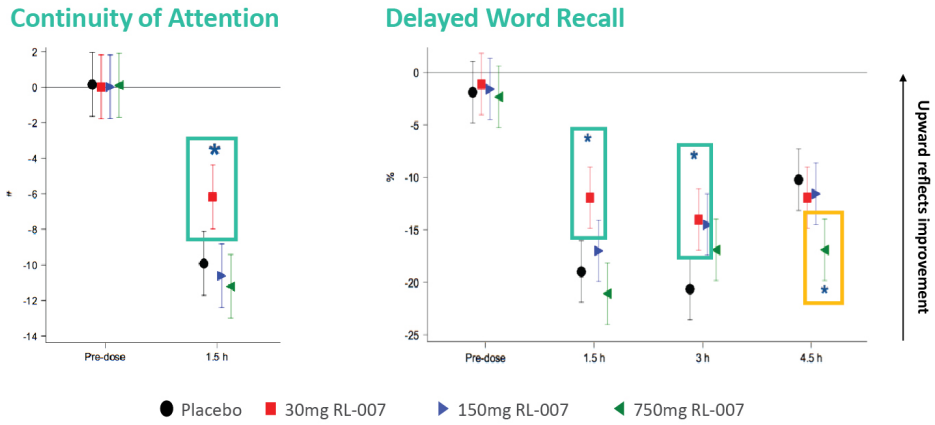
scopolamine challenged dogs, RL-007 demonstrated enhanced effects on cognition. In the figure below, investigators observed enhanced learning and memory with an inverted U-shaped dose response.



* = P<0.05 vs baseline or scopolamine-treatment; n=6 dogs/treatment; BID for 3 days prior to scopolamine challenge.
Study Report: BIO-09-745

Phase 1 Scopolamine Challenge

A Phase 1 study enrolled 23 healthy volunteers to evaluate the effect of RL-007 on the scopolamine cognition model in healthy volunteers. RL-007 was administered ter in die, or three times a day ("TID") for one day and then co-administration with scopolamine on Day 2 to induce a temporary cognitive impairment. RL-007 was well tolerated. A statistically and clinically significant reversal of the scopolamine-induced cognitive impairment was observed with the 30 mg TID dose. Additionally, marked changes in quantitative encephalogram ("qEEG") were found at all doses tested. Notably, and consistent with non-clinical evidence, the dose response was inverted U-shaped, with the most significant changes observed at the 30mg dose-level.



*CSR 209323-502; P<0.05, n=18, CNS effects also monitored by EEG.
1: Keith Wesnes in CDR study report

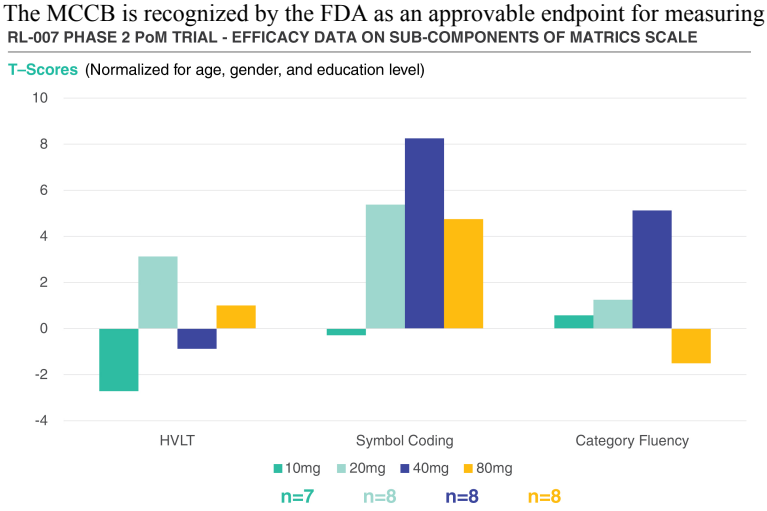
Phase 2 Study in Diabetic Peripheral Neuropathic Pain ("DPNP")

A Phase 2 study that enrolled 181 patients with DPNP in a double-blind, randomized, placebo-controlled study to evaluate the efficacy of RL-007 to address neuropathic pain in subjects with diabetes. While unsuccessful in demonstrating a clinically meaningful effect on pain scores with RL-007, as part of this trial, cognitive function was assessed using a standard computerized cognitive test battery, Cogstate, which assessed cognitive abilities such as attention, concentration, verbal learning and memory, working memory and global cognitive functioning. In addition, investigators observed subjects in the lowest dose cohort (40/80 mg) exhibited an improvement in verbal learning (Cohen's d = 0.31) and memory (Cohen's d = 0.36), underscoring the effects on cognition and inverted-U dose response observed in prior clinical and non-clinical studies.

Phase 2a Study in CIAS

Recognify initiated a Phase 2a proof-of-mechanism study in the United States for RL-007 in 32 CIAS patients. The study was designed to evaluate the safety and tolerability of RL-007, as well as effects on clinical activity endpoints, including a subset of the MATRICS Consensus Cognitive Battery ("MCCB") to assess cognition. In December 2021, we announced positive clinical data from the Phase 2a study of RL-007 in CIAS patients. RL-007 was well tolerated and demonstrated a clinically meaningful pro-cognitive profile consistent with previous Phase 1 and Phase 2 trials of this compound.

In the figure below, we show the results on a subset of the MATRICS Consensus Cognitive Battery (MCCB) demonstrating an inverted-U dose response on the key cognitive endpoints of HVLT, symbol coding and category fluency. On symbol coding at the 20mg dose, a Cohen's d of 0.79 was observed. The MCCB is recognized by the FDA as an approvable endpoint for measuring cognitive function in CIAS.



The totality of the results observed in this Phase 2a study supported the progression of RL-007 in clinical development to further demonstrate the pro-cognitive benefit of RL-007 in CIAS.

- **Recent Advancements:** In the first quarter of 2023, we announced the dosing of the first patient in the Phase 2b proof-of-concept clinical trial for RL-007 in CIAS. The Phase 2b trial is a randomized, placebo-controlled, double-blind, three-arm study evaluating 20mg and 40mg of RL-007 compared to placebo in approximately 230 patients The primary endpoint of the study is the MCCB neurocognintive composite score at 6 weeks. We anticipate reporting top-line results from this study by mid-2025.

GRX-917 (deuterated Etifoxine)

- **Product Candidate Concept:** GRX-917 is a novel compound that potentiates neurosteroidogenesis, that is being developed as a treatment for Generalized Anxiety Disorder ("GAD").

GRX-917 is a deuterated form of etifoxine (Stresam®), an anxiolytic drug approved in France and other countries. Etifoxine has demonstrated rapidity of onset and magnitude of efficacy comparable to benzodiazepines in the treatment of anxiety-related disorders. Additionally, etifoxine's safety profile has been reported to be superior to benzodiazepines, with less sedation, cognitive impairment, amnesia or ataxia, and minimal human abuse liability.

In contrast to benzodiazepines, etifoxine and GRX-917 appear to produce their anxiolytic effects by enhancing neurosteroidogenesis and thus increasing the concentration of endogenous brain neurosteroids, including allopregnanolone. Allopregnanolone is a potent positive allosteric modulator of the $GABA_A$ receptor which, in the presence of GABA, results in further attenuation of neuronal activity. GRX-917 does not activate the $GABA_A$ receptor at clinically efficacious concentrations.

The pharmacological profile of GRX-917 has been evaluated and compared to etifoxine in a series of pre-clinical studies, which have demonstrated that GRX-917 has similar efficacy and pharmacology to etifoxine. GRX-917 has been observed to have improved metabolic stability conferred by deuteration compared to etifoxine.

- **Disease Overview:** Anxiety disorders develop when feelings of apprehension and worry are excessive, persistent and/or markedly impact a person's quality of life. Anxiety disorders can present with a range of symptoms and may impact personal health, as well as both social and professional interactions. There are several types of anxiety disorders, including GAD, social anxiety disorder and panic disorder, which are distinct but share common symptoms.

  Anxiety disorders are generally treated with medication, psychotherapy or both. First line pharmacotherapy often involves use of antidepressants, including SSRI/SNRIs. SSRI/SNRIs work by increasing levels of serotonin in the brain, but they typically have a slow onset of action, requiring treatment for four to six weeks before significant therapeutic benefits are observed, and maximal benefits often requiring up to twelve weeks of treatment. SSRIs also have a number of side effects, including sexual dysfunction, insomnia and gastrointestinal disturbances.

  Benzodiazepines are also used to treat anxiety and can offer rapid reduction of symptoms, with relief as soon as thirty minutes after administration. However, many patients experience sedative side effects resulting in drowsiness or lethargy, decreased mental sharpness, slurring of speech and decreased coordination. The long-term use of benzodiazepines is associated with the development of tolerance and dependence, making discontinuing such medications challenging for most patients.

- **Prior Evidence – Non-Clinical & Clinical Data:**

  Etifoxine & GRX-917 Non-Clinical

  Etifoxine and GRX-917 have shown anxiolytic effects in the elevate plus maze ("EPM") mouse model. Finasteride, an inhibitor of neurosteroid biosynthesis, was able to fully inhibit the anxiolytic activity of GRX-917 and etifoxine in the EPM model, suggesting that both compounds work via modulation of neurosteroidogenic activity. In humans, the anxiolytic activity of etifoxine hydrochloride is not inhibited in the presence of the benzodiazepine antagonist flumazenil (Schlichter et al, 2000), supporting the notion that etifoxine's anxiolytic effects are not driven by the direct activation of the benzodiazepine site of the $GABA_A$ receptor.

  GRX-917's half-life in human and rat liver microsomes is increased by 82% compared to etifoxine. In rats, this enhanced in-vitro metabolic stability translated in-vivo to a 1.7-fold increase in maximum concentration (i.e. Cmax) and a 2.5 fold increase in exposure (i.e. AUC) for the GRX-917 compared to etifoxine. Terminal half-life was also increased by 20%. The effect of deuterium substitution on enhancing microsome stability is identical (+82%) in rats and humans, pointing to a similar metabolic pathway. Therefore, GRX-917's superior rat PK profile is expected to translate to humans.

  Phase 1 Safety, Tolerability and PK Study of Etifoxine

  In 2020, GABA Therapeutics completed a Phase 1 study of etifoxine to evaluate the safety, tolerability, PK and PD (via qEEG) of single (100 mg) and multiple doses (100 mg, twice a day ("BID") for seven days) of oral etifoxine in normal healthy volunteers. The results quantified the PK of etifoxine and served as a benchmark for the single and multiple ascending dose study GRX-917.

  Phase 1 Single and Multiple Ascending Dose Study

  In June 2021, GABA initiated a Phase 1 single and multiple ascending dose trial of GRX-917. The Phase 1 trial was a randomized, double-blind, placebo-controlled study of the safety, tolerability and PK of single and multiple-ascending doses of GRX-917 up to 500mg as single doses and 300mg given every twelve hours for seven days, respectively.

  In January 2023, Phase 1 results were announced from the study of GRX-917 in healthy volunteers. GRX-917 was well-tolerated, in all dose cohorts with no dose-limiting toxicities and sedation compared to placebo.

  Additionally, the data confirmed an improved PK profile including longer half-life and increased bioavailability compared to etifoxine. Quantitative electroencephalography ("qEEG") data showed dose-dependent increases in frontal beta power, providing evidence of target engagement. These qEEG data from the Phase 1 study were detailed in April 2023 in a poster at the Society for Biological Psychiatry ("SOBP") Annual Meeting.

  Regulatory Authorities Pharmacovigilance assessments of Etifoxine

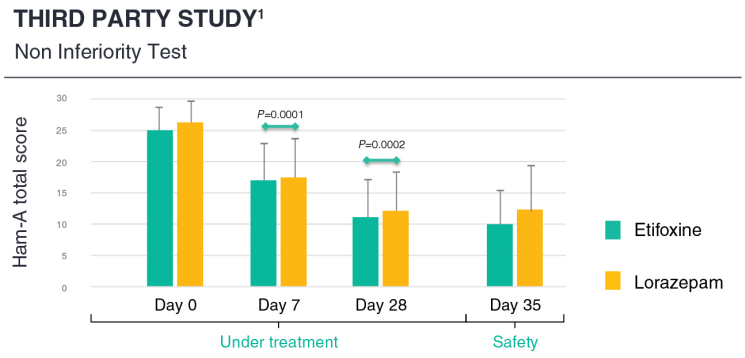
  An analysis of the safety profile of etifoxine (2000-2012) was completed by the French National Agency for the Safety of Medicines and Health Products ("ANSM") France showed that the profile of Adverse Drug Reaction (ADR) is globally similar to that expected and there were no new safety data regarding the risks identified in the spontaneous reporting data. In over 14 million prescriptions of Stresam® between 2000 and 2012, there was a low ADR rate of ~ 21 per million treatments. There

were only sporadic reports of ADRs relating to abuse, misuse or dependence. Data from this pharmacovigilance study were reviewed by the ANSM and this resulted in a confirmation of the favorable risk-benefit assessment subject to the conduct of additional studies. As risk mitigation measures, revisions were made to the label information and a letter was sent to healthcare professionals in 2014.

Further to the ANSM's study, in 2021 the ANSM initiated a referral towards the European Medicines Agency ("EMA") leading to a review of Stresam's (etifoxine) benefit-risk based on additional available data including the results of a new study. The review was carried out by the EMA's Committee for Medicinal Products for Human Use ("CHMP") which concluded that Stresam can continue to be used for the treatment of anxiety disorders, but it must not be used in patients who previously had severe skin reactions or severe liver problems after taking etifoxine.

Third-Party Non-Inferiority Study of Etifoxine vs. Lorazepam

A third-party conducted a study to compare the efficacies of etifoxine (50mg TID) and lorazepam (.5 – 1mg BID) monotherapies in the treatment of adjustment disorder with anxiety over a period of 28 days. The study demonstrated that etifoxine works as rapidly as lorazepam, with etifoxine continuing its effects beyond the treatment period, while lorazepam shows rebound post-treatment.



1. Nguyen et al., "Efficacy of etifoxine compare to lorazepam monotherapy" (2006)

- **Recent Advancements:** Following Phase 1 results announced in January 2023, the company is actively looking for partnership and external funding opportunities for this program. The goal is to proceed GRX-917 into a Phase 2 study in patients living with anxiety disorder.

Our Other Clinical Program

Perception Neuroscience: PCN-101 (R-Ketamine) for TRD

- **Product Candidate Concept:** PCN-101, a subcutaneous formulation of R-ketamine, as a therapy for psychiatric indications, initially focused on TRD. PCN-101 is being evaluated as a rapid-acting antidepressant therapy with potential benefits over S-ketamine, including a non-dissociative profile that has the potential to allow for at-home-use.
- **Prior Clinical Evidence:** In a third-party, open-label clinical trial, another formulation of R-ketamine was observed to produce a rapid and durable response with limited dissociative side effects in a small number of patients with TRD.

In January 2023, results from the Phase 2a proof-of-concept study were announced. The objective of this study was to assess the efficacy of PCN-101 for the two doses, 30 mg and 60 mg, which were sub-dissociative and non-sedating based upon Phase 1 results. To achieve a sufficiently differentiated and commercially viable treatment in TRD in line with our internal target product profile, we set the following targets for the single dose Phase 2a study. On efficacy, we targeted a placebo adjusted change from baseline of 5 or more points on the MADRS at 24 hours, the primary endpoint. On safety/tolerability, we targeted sedation and dissociation comparable to placebo, operationalized as a risk ratio of less than 2. The observed mean change from baseline on the MADRS at 24 hours was -15.3 for PCN-101 60 mg and -13.7 for placebo (placebo adjusted change of -1.6; p-value 0.5). The magnitude of both the placebo effect and the drug effect were comparable to that seen in several other acute antidepressant trials incorporating inpatient overnight stays. The efficacy of the 60 mg dose was greater when considering only US sites at the 24-hour time point, though the placebo effect was similar to that observed in the full sample set (-19.2 MADRS mean change from baseline on 60mg PCN-101 vs. -14.4 on placebo; p-value 0.32). However, it should be noted that the

number of patients in the US-only subset was small (9 on PCN-101 and 8 on placebo). The single 60 mg dose of PCN-101 showed an efficacy signal at each timepoint over the 2-week timeframe of the study, potentially indicating a sustained duration of effect. The results did reach statistical significance (p-value 0.04) at the 15-day endpoint in the US-only subset in an exploratory analysis. PCN-101 was generally well-tolerated with rates of sedation and dissociation comparable to placebo.

- **Recent Advancements:**
  - In August 2023, we reported results from the Phase 1 open-label bridging study designed to assess the safety, tolerability, and PK profile of 60mg, 90mg and 120mg of PCN-101 delivered subcutaneously ("SQ") as compared to 60mg of PCN-101 delivered via IV.
  - PK analysis indicated that 120mg of PCN-101 delivered SQ resulted in an approximate doubling of drug exposure ("AUC") while maintaining approximately the same maximum concentration ("Cmax") as the 60mg IV dose.
  - At the highest SQ dose of 120mg, rates of sedation (defined as MOAA/S score <5) and dissociation (defined as CADSS total score >4 and change from baseline >0) were each 14%. Overall, we believe the data supports testing the concept of at-home use of PCN-101 in future studies.
  - We continue to work collaboratively with Perception Neuroscience to explore strategic partnership opportunities.

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 potential products 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. These treatments are typically used alongside antidepressants and other treatments used in earlier lines of therapy for depression. 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 and which is also being studied in TRD. Psychosocial interventions and non-pharmacological, somatic treatments may also be used for patients. We are aware of several

biopharmaceutical companies with therapies in development for TRD and MDD including Sage Therapeutics, Axsome Therapeutics, GH Research, The Janssen Pharmaceutical Companies of Johnson & Johnson, Cybin, Neumora Therapeutics, Relmada Therapeutics, 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 Boehringer Ingelheim and Takeda Pharmaceuticals (in partnership with Neurocrine Biosciences). Other companies with therapies in development in schizophrenia not focused on CIAS that we are aware of include Boehringer Ingelheim, Karuna Therapeutics (since acquired by Bristol-Myers Squibb Company), Minerva Biosciences, Neurocrine Biosciences, and Takeda Pharmaceuticals.

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, Bionomics and MindMed, Sumitomo Pharmaceuticals, 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 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 December 31, 2023, our intellectual property portfolio includes 33 issued U.S. patents, 223 issued non-U.S. patents, 45 pending U.S. patent applications, 111 pending non-U.S. patent applications, 20 pending U.S. provisional applications, and 28 PCT applications. Our intellectual property portfolio for each of the programs in our pipeline 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
BPL-003	✓	✓	✓	✓
VLS-01	✓	✓	✓	✓
ELE-101	✓		✓	
IBX-210	✓		✓	
EMP-01			✓	✓
EGX-A & EGX-B	✓	✓	✓	✓
RL-007	✓	✓	✓	✓
GRX-917	✓	✓		✓
PCN-101	✓		✓	✓
KUR-001			✓	✓
RLS-01			✓	✓

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

A description of our patents as of December 31, 2023, follows below:

BPL-003

Beckley Psytech owns two issued U.S. patents, three foreign issued patents in Europe, two issued patents in the United Kingdom, two U.S. pending patent applications, nine foreign pending patent applications in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand, two PCT patent applications and numerous pending United Kingdom priority patent applications covering benzoate salt of 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT benzoate), methods of synthesis, methods of use, crystalline forms and formulations thereof. Atai Therapeutics, Inc. has a strategic investment in Beckley Psytech to accelerate the clinical development of short-duration psychedelics.

VLS-01

ATAI Therapeutics, Inc. owns one issued U.S. patent, three U.S. pending patent applications and two PCT patent application, two U.S. provisional patent applications and twenty nine foreign pending patent applications in Argentina, Taiwan, Australia, Brazil, Canada, Chile, China, EP, 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 (VLS-01), (iii) DMT parenteral formulations, and (iv) oral transmucosal films of DMT. 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 one issued U.S. patent, eight U.S. pending patent applications, five PCT patent applications, one U.S. provisional patent applications and seventeen pending foreign applications in Australia, Brazil, Canada, Chile, China, EP, 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. 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.

ELE-101

Beckley Psytech owns two issued U.S. patents, two U.S. pending patent applications, one PCT patent application and nine foreign pending patent applications in Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea and New Zealand. Beckley Psytech also co-owns with Board of Supervisors of Louisiana State of University and Agricultural and Mechanical College one U.S. pending patent application and one foreign pending patent application in Europe covering methods of use of 4-hydroxy-N,N-dimethyltryptamine (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.

IBX-210

ATAI Therapeutics, Inc. owns five issued U.S. patents and six foreign issued patents in Europe, Australia, Canada and Hong Kong, six U.S. pending patent applications, and two foreign pending patent applications in Australia and South Africa covering methods of treatment using ibogaine (IBX-210). DemeRx IB's issued patents and any patents issuing from the pending applications, if granted, are expected to expire in 2035, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Atai Therapeutics, Inc. owns one pending U.S. patent application and one pending PCT patent application, covering methods of improving the therapeutic effectiveness and safety profile of ibogaine. Any patents issuing from these pending patent applications, if granted, are expected to expire in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EMP-01

EmpathBio Inc. owns one issued U.S. patent, eight U.S. pending patent applications, six PCT patent applications and two U.S. provisional patent applications, covering MDMA enantiomers and processes for the preparation of MDMA, its enantiomers and derivatives thereof. 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 one U.S. pending patent application, one PCT patent application, and one provisional application covering salts of R-MDMA and polymorphic forms and compositions comprising R-MDMA and methods of treating with the same. Any patents issuing from this pending patent application, if granted, are expected to expire between 2043 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. ATAI Therapeutics Inc. owns one U.S. pending patent applications, one PCT patent applications and four U.S. provisional 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 one issued U.S. patent, two U.S. pending patent applications, four PCT patent applications, fourteen foreign pending patent applications in Australia, Brazil, Canada, Chile, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia and UAE and four U.S. provisional patent applications covering novel 5-HT2A agonists. Atai Therapeutics, Inc, owns two U.S. pending patent applications, one PCT patent application and one U.S. provisional patent application covering non-hallucinogenic 5-HT2A agonists. Atai Therapeutics, Inc. owns two U.S. provisional patent applications covering EGX-A/EGX-B development related filings. Any patents issuing from these pending patent applications, if granted, are expected to expire between 2041 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

RL-007

Recognify in-licenses twelve issued U.S. patents and 36 foreign issued patents in Europe, Australia, Brazil, Canada, China, Hong Kong, Israel, South Africa, 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.

GRX-917

GABA Therapeutics owns four issued U.S. patents, two U.S. pending patent applications, eleven issued foreign patents in Australia, Brazil, Canada, China, Europe, Mexico, Israel, Japan, Republic of Korea and Mexico and one foreign pending patent application in Israel and one PCT application, covering the pharmaceutical composition and corresponding methods of use of the deuterated analogs of etifoxine (GRX-917). GABA Therapeutics' issued patents and any patents issuing from the pending patent applications, if granted, are expected to expire between 2036 and 2044, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

PCN-101

Perception Neuroscience in-licenses three issued U.S. patents, three foreign issued patents in Japan and two foreign issued patents in Europe and Canada, four U.S. pending patent applications and fifteen foreign pending patent applications in Brazil, Canada, China, Europe, Hong Kong, and Japan covering the composition of and methods of using R-ketamine (PCN-101) for the treatment of depressive symptoms in mental disorders, neurological disorders and substance abuse. Perception Neuroscience also in-licenses one U.S. pending patent application and one foreign issued patent in Australia and seven foreign pending patent applications in Brazil, Canada, China, Europe, Hong Kong, Israel and Japan covering the composition of matter of S-Norketamine for the treatment of depressive symptoms. Perception Neuroscience also owns one issued U.S. patent, one U.S. pending patent application, one foreign issued patent in Mexico, and seven foreign pending patent applications in Australia, Canada, China, Europe, Hong Kong, Japan and Mexico covering the method of using R-ketamine (PCN-101) for the treatment of depressive symptoms in mental disorders and substance abuse, as well as two pending PCT application directed to R-Ketamine salts and pharmaceutical compositions and one PCT application directed to methods of administering R-Ketamine. Perception Neuroscience's owned and in-licensed issued patents and any patents issuing from the owned or in-licensed pending patent applications, if granted, are expected to expire between 2034 and 2043, 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 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, or CMS, DEA, and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome 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. Additionally, some significant aspects of regulation in the European Union ("EU"), are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Certain of our product candidates may be subject to regulation as combination drug-device products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, we believe the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval of our product candidates regulated as combination drug/devices. We do not anticipate that the FDA will require a separate medical device authorization for the device, but this could change during the course of its review of any marketing application that we may submit.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under 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. 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. Some non-clinical testing may continue even after the IND is submitted. 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. An IND must become effective before human clinical trials may begin. 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 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, and 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.

Furthermore, 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. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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, or 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, or 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. 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.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. An NDA is 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.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for

this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if a product candidate is determined to be contained within the competitor's product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to extensive 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 also are 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, or 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 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.

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, or 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, or 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 Co-operation and Development 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, or ICH, guidelines on Good Clinical Practices, or GCP, 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, or 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, or 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

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

Marketing Authorization

In order to market our future 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, or 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, or CHMP, of the European Medicines Agency, or 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 biotechnology processes, such as genetic engineering, (ii) designated orphan medicines, (iii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases and (iv) advanced therapy medicinal products, or 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, or 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.

Orphan medicinal products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. In the EU a medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating; (2) either (a) condition such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication which means that the competent authorities cannot accept another MAA or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where the prevalence of the condition has increased above the threshold or it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, MA may be granted to a similar product for the same indication at any time if (1) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (2) the applicant consents to a second orphan medicinal product application; or (3) the applicant cannot supply enough orphan medicinal product. A company may voluntarily remove a product from the orphan register.

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, or UN, Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971, or 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, or PSURs.

All new MAA must include a risk management plan, or 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, or 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.

Regulation of combination products in the EU

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. EU guidance has been published to help manufacturers select the right regulatory framework.

Drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. The EMA is responsible for evaluating the quality, safety and efficacy of MAAs submitted through the centralized procedure, including the safety and performance of the medical device in relation to its use with the medicinal product. The EMA or the EU member state national competent authority will assess the product in accordance with the rules for medicinal products described above but the device part must comply with the Medical Devices Regulation (including the general safety and performance requirements provided in Annex I). MAA must include – where available – the results of the assessment of the conformity of the device part with the Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the MAA does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the competent authority must require the applicant to provide a notified body opinion on the conformity of the device.

By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are co-packaged, for example), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the Medical Devices Regulation.

The characteristics of non-integral devices used for the administration of medicinal products may impact the quality, safety and efficacy profile of the medicinal products. To the extent that administration devices are co-packaged with the medicinal product or, in exceptional cases, where the use of a specific type of administration device is specifically provided for in the product information of the medicinal product, additional information may need to be provided in the MAA for the medicinal product on the characteristics of the medical device(s) that may impact on the quality, safety and/or efficacy of the medicinal product.

The requirements regarding quality documentation for medicinal products when used with a medical device, including single integral products, co-packaged and referenced products, are outlined in the EMA guideline of July 22, 2021, which became applicable as of January 1, 2022.

The aforementioned EU rules are generally applicable in the EEA.

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; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; 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 (beginning 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. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.
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.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. 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. 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 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. 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 concerns, we're dedicated to accelerating patient access to evidence-based innovation in mental health. 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 healing mental health disorders so that everyone, everywhere can live a more fulfilled life.

As of December 31, 2023, we had 83 full-time employees and five contractors or consultants doing regular work for the company. Of our full-time employees, 39 focus on driving forward research and development programs (including Digital Therapeutics), 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 UK and Germany.

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, the Company identified redundancies among certain positions, which resulted in a reduction in force of approximately 10% of the Company's global workforce.

Our four core atai values are: Conscious Care, Bold Entrepreneurship, Collaborative Innovation, and Radical Responsibility. 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

In response to evolving needs, we've reimagined our talent acquisition strategy by realigning responsibilities. Our HR team and hiring managers have taken the lead in recruitment, leveraging their extensive networks for our current hiring requirements. Committed to attracting top-notch talent, we maintain a focus on delivering a stellar recruiting process and exceptional candidate experiences. As we navigate this new approach, we are continuously exploring innovative avenues to connect with and recruit highly skilled individuals.

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:

- **Conscious Care**: We act in service of our ultimate goal: to heal mental health disorders for all while caring for ourselves and our team.
- **Bold entrepreneurship**: We are "loosely coupled and tightly aligned" as we strive for excellence over perfection, fast and focused to accelerate innovation for patients**.**
- **Innovative Collaboration**: Individuals and teams work together with good humor and no drama, valuing different perspectives and diversity of thought, background, nationality, and style.
- **Radical Responsibility**: We take full responsibility for our circumstances. We grow and learn from failures.

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. The Code of Conduct is available in the "Governance Overview" section of our website under "Corporate Governance," which is located at https://ir.atai.life.

Total Rewards and Employee Engagement

To attract and retain top talent, we offer a competitive total rewards package. We target pay at the 50th percentile of market, based on Aon Radford data, and employee stock option grants between the 50th and 75th percentile or above. We link a portion of every employee's compensation to performance through a performance bonus program. We also incentivize subsidiary-level employees to achieve specific milestones at core value-inflection points, such as IND or NDA approval.

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.

Diversity, Equity and Inclusion

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

Hybrid office culture

As of December 31, 2023, we had offices in Berlin, New York, and San Diego. We aim to foster a hybrid culture where we encourage employees to work in the office two or three days per week, but with the option to work from home when business needs allow for it. We do this because we believe the office offers meaningful benefits in terms of employee mental health and social connection; serendipitous conversations leading to greater creativity and cross-functional collaboration; and important opportunities for more junior staff to learn via exposure and osmosis.

atai Impact

In October 2021, we announced the launch of our philanthropic program, atai Impact, 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 million atai Fellowship Fund will facilitate 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.life. All reports we file with the SEC are available for download free of charge via the Electronic Data Gathering Analysis and Retrieval (EDGAR) System on the SEC's website at www.sec.gov. We also make electronic copies of our reports available for download, free of charge, through our investor relations website at *ir.atai.life* 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.

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.

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, 2023 and 2022 was $40.2million and $152.4 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 U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Authority, or the 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, 2023, we had $154.2 million in cash and cash equivalents and short-term investment securities. Based on our current operating plan, we estimate that our existing cash, 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 2026. 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. 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, or 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 board of supervisory directors 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, at December 31, 2023, we had an effective shelf registration statement filed with the SEC in July 2022 registering $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 remains available. 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, or 2021 Incentive Plan, we are authorized to grant various stock-based awards to our executive officers, directors, employees and consultants. If our board of supervisory directors 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, 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 and as further amended in May 2023 (collectively, the "Loan Agreement"), with Hercules Capital, Inc., or 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 Limited ("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 statement 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.

The active ingredients used in some of our product candidates have been associated with risks that may lead to our product candidates not being approved, and even if approved, may lead to insufficient physician or consumer acceptance given the severity of the risks. For example, we are developing ibogaine as DMX-1002 for the potential treatment of opioid use disorder. 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 risk, inadequate cardiac monitoring and drug product of unknown purity and concentration. The considerations involved in the administration of ibogaine are complex and depend on the medical profile of individual patients, and we may not be successful in demonstrating an acceptable approach to manage the severity of the risks.

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. 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.

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

We maintain the majority of our cash and cash equivalents in accounts at various third-party U.S. and multinational financial institutions, and our deposits at certain of these institutions exceed the $250,000 Federal Deposit Insurance Corporation ("FDIC") insurance limit. Market conditions can impact the viability of these institutions. In the event of a future failure or closure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all, and there is no guarantee that the Federal Reserve Board, the U.S. Treasury Department and the FDIC will provide access to uninsured funds in a timely fashion or at all.

Any inability to access or delay in accessing these funds could adversely impact our business, results of operations, financial position, and liquidity.

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.

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 Investigational New Drug Applications, or 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 set of patients or disorder indications, 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 and the rate of dropout among clinical trial participants. 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. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

In addition, clinical trial design for some of our product candidates can be complex given their characteristics. For example, we will need to design clinical trials for certain product candidates to evaluate efficacy across a range of doses. Additionally, we may utilize an "open-label" trial design for some of our future clinical trials. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Patients selected for early clinical studies often include the most severe sufferers, and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The opportunity for bias in clinical trials as a result of open-label design may not be adequately handled and may cause any of our trials that utilize such design to fail or to be considered inadequate and additional trials may be necessary to support future marketing applications. 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 cognitive impairment associated with schizophrenia, or 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 European Union, or EU, has continued to evolve. The EU Clinical Trials Regulation, or 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 clinical trial application, or 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as 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, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board, or 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, or 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 good clinical practice requirements, or 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 adverse events, or 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 U.S. Drug Enforcement Administration, or 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, or the 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 therapeutic candidates containing controlled substances. In addition, therapeutic 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 United Nations, or UN, Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971, or 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. 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 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 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.

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 major depressive disorder, or 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 potential products 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 risk, inadequate cardiac monitoring and drug product of unknown purity and concentration. In addition, although mitragynine, the primary alkaloid in kratom and the one thought to drive its effects, is believed to have a lower risk of both inducing respiratory depression and abuse than typical opioids, both phenomena have been associated with kratom use in scientific literature. 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 risk evaluation and mitigation strategy, or 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 lengthy 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. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. 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.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in international markets. If we fail to comply with regulatory requirements in any markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

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, 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.

The complexity of a combination product that includes a drug or biologic and a medical device, including a digital therapeutic, presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval of our product candidates.

We may decide to pursue marketing authorization of a combination product comprised of drug candidates and medical devices. A combination product includes, amongst other possibilities, a combination of a drug and device intended to be used together, according to their proposed labeling where both are required to achieve the intended use, indication or effect.

Developing and obtaining regulatory approval for combination products pose unique challenges because they involve components that are regulated by the FDA pursuant to different regulatory frameworks and by different FDA centers. As a result, such products raise regulatory, policy and review management challenges. For example, because divisions from both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health must review submissions concerning product candidates that are combination products comprised of drug and devices, the regulatory review and approval process for these products may be lengthened. In addition, differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post-approval modifications. Similarly, the device components of our product candidates will require any necessary approvals or other marketing authorizations or certifications in other jurisdictions, which may prove challenging to obtain. Such complexities in developing combination products may therefore adversely impact our development plans and our ability to obtain regulatory approval for our product candidates.

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. Thus, 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.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval

pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing product candidates for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or the FDCA. Section 505(b)(2) permits the filing of a NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer, depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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 current Good Manufacturing Practice, or 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 marketing authorization application, 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 Phase 4 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. 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 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 and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We 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, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain 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. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. We may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, California enacted the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, 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. 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. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

In Europe and the UK, we are subject to the European Union General Data Protection Regulation 2016/679 and applicable national supplementing laws, or the EU GDPR**,** and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 or the 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, or the 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, or the 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.

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, or 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, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 percent (effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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, or ASP, plus 6 percent to ASP minus 22.5 percent on specified covered outpatient drugs, or SCODs, 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, or 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. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which 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, 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 (beginning 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. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 drugs 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 Sage Therapeutics, Axsome Therapeutics, GH Research,The Janssen Pharmaceutical Companies of Johnson & Johnson, Cybin, Neumora Therapeutics, and Relmada Therapeutics; CIAS, including from Boehringer Ingelheim, Karuna Therapeutics (since acquired by Bristol-Myers Squibb Company), Minerva Biosciences, Neurocrine Biosciences, and Takeda Pharmaceuticals; SUD, including from BioXcel, Indivior, and Intra-Cellular Therapies; anxiety, including from VistaGen Therapeutics, Bionomics and MindMed, Sumitomo Pharmaceuticals, 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 potential 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. Such therapists are typically employed by the third-party therapy sites. 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.

Although we currently provide training and expect to continue providing training to the therapists (directly or through third-party providers), 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. However, if not properly

managed and supervised, 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 do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture drug supplies for our ongoing clinical trials or any future clinical trials that we may conduct, and we lack the resources to manufacture any product candidates on a commercial scale. We 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 pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products 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, 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.

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 United States Patent and Trademark Office, or 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 abbreviated new drug application, or 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 stockholders, 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 PTA for patents in families where related patents have issued without PTA. Thus, 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, Florian Brand, our Chief Executive Officer, and Srinivas Rao, our Chief Scientific 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 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. 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 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 and significant disruption of our business operations which could materially affect our results.

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 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"). Our IT systems and those of current and future third parties on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from cyber incidents, employee error or malfeasance, misconfigurations, "bugs" or other vulnerabilities, theft or misuse, sophisticated nation-state and nation-state-supported actors, 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 computer systems and networks, have increased in frequency, intensity, and sophistication. These threats pose a risk to the security of our, our programs', our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, 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 systems, networks and Confidential Information.

The risk of a security breach or disruption, 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 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. 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 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 clinical and other data that is stored on their systems. Any loss of 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 data. 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 networks, such as through phishing scams and ransomware. Although we do not believe that we have experienced any significant 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 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 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. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

Disruptions at the FDA, the U.S. Securities and Exchange Commission, or the SEC, and other U.S. and foreign government agencies caused by funding shortages, 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, over the last several 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.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if 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, New York, and San Diego. 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, or the 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.

The United Kingdom's and Gibraltar's withdrawal from the European Union and the European Economic Area may have a negative effect on global economic conditions, financial markets and our business.

We are a multinational company with worldwide operations, including significant business operations in Europe.

Since January 1, 2021, the UK operates under a distinct regulatory regime to the EU. EU pharmaceutical laws only apply in respect of the UK to Northern Ireland (as set out in the Protocol on Ireland/Northern Ireland). EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". While the UK has indicated a general intention that new laws regarding the development, manufacture and commercialization of medicinal products in the UK will align closely with EU law, there are limited detailed proposals for future regulation of medicinal products. Therefore, there remains political and economic uncertainty regarding to what extent the regulation of medicinal products will differ between the UK and the EU in the future. Any divergences will increase the cost and complexity of running our business, including with respect to the conduct of clinical trials.

Equally, the British Overseas Territory of Gibraltar left the European Union and the European Economic Area on December 31, 2020. On December 31, 2020, the Governments of Gibraltar, the United Kingdom and Spain reached a temporary agreement under which Gibraltar would join the European Union's Schengen Area thereby clearing the way for the European Union and the United Kingdom to commence formal negotiations on a treaty between the European Union, Spain, the United Kingdom and Gibraltar concerning the movement of labor and goods, the environment, citizens' rights and other areas of trade and cooperation. There is no certainty that such deal will be concluded nor by what time or on what terms.

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global political, regulatory, economic or market conditions and the stability of political institutions as well as global financial markets and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates, interest rates and credit ratings have been and may continue to be subject to increased market volatility. Lack of clarity about future United Kingdom laws and regulations as the United Kingdom determines which EU laws to replace or replicate (including whether to replicate only in part or on different terms), including free trade agreements, commercial regulatory permissions including clearances and approvals, tax and customs laws, intellectual property rights, environmental, health and safety laws and regulations, data protection laws including with respect to transfers, immigration laws, employment laws and transport laws could increase costs, disrupt supply chains, depress economic activity and restrict our access to capital. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and this could adversely affect the value of the euro and the price of our shares.

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.

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, including if we qualify as a "large accelerated filer," in which case we would no longer be an emerging growth company as of the fiscal year-end.

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 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. 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 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 and/or the 45% tests in Rule 3a-1 thereof, as described in the second bullet point above. 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 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) and/or Rule 3a-1. 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) and/or Rule 3a-1. 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 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 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.

The U.S. Treasury recently proposed regulations that may change certain aspects of the PFIC rules described above, including the application of certain elections to partnerships and similar entities. It is unclear whether such proposed regulations would 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 Organization for Economic Cooperation and Development ("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 our place of effective management, the tie-breaker rule taken up in the double tax treaty between Germany and the Netherlands, or 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. 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, or the 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.

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, 2023, our German NOL carryforward was approximately $162.4 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, 2023, we had U.S. federal NOLs of $52.3 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 stockholders" 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, 2023, Apeiron held an 19.7% 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, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of 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. In addition, substantially all of our assets are located outside 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 the Hague Convention on Choice of Court Agreements entered into force for the Netherlands, but has not entered into force for the United States. Accordingly, 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 foreign judgment if (i) the jurisdiction of

the foreign court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the foreign 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 foreign judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the foreign 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 foreign 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 foreign judgment is given binding effect, a claim based thereon may, however, still be rejected if the foreign judgment is not or no longer formally enforceable.

In addition, actions brought in a Dutch 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 or complicating factors. In particular, Dutch courts will apply Dutch private international law to determine the law applicable to such a claim, which rules may lead to applicability of a different law than U.S. law. Dutch courts do not award punitive or exemplary damages. Litigation in the Netherlands 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. Dutch procedural law differs greatly from U.S. law with respect to pre-trial discovery and the disclosure of evidence during trial. Proceedings in the Netherlands would, in principle, have to be conducted in the Dutch language. For these reasons, it may be difficult for a U.S. investor to bring an original action in a Dutch court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our executive officers, directors and senior management. Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our managing directors, supervisory directors, representatives or certain experts named herein who are residents of the Netherlands or 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 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, its 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 or our former CEO, as applicable, to manage our affairs if all of our managing directors and supervisory directors are removed from office and to appoint others to be charged with the management and supervision of our affairs, until new managing directors and 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, or 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 they do 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.

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 have previously disclosed a material weakness in our internal control over financial reporting in our consolidated financial statements for the fiscal year ended December 31, 2021. While management has concluded that the previously identified material weaknesses in internal control over financial reporting were remediated as of December 31, 2022, we can give no assurance that additional 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. 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.

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 and 2023, we implemented certain cost

reduction efforts to reduce material spend and operating expenses. In February 2023, we restructured our workforce and eliminated approximately 30% of our global workforce in order to more effectively allocate our research and development and other resources to support the revised business and program priorities and to reduce operational costs. 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 public company compliance initiatives and corporate governance practices.

As a 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, such as the COVID-19 pandemic, 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.

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.

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. If we are not effective in addressing environmental, social, and governance matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. 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. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

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.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate. These regulations, which may differ across jurisdictions, 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. Our supply chain would likely be subject to these same transitional risks and would likely pass along increased costs to us.

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 "*Cyberattacks 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 and significant disruption of our business operations which could materially affect our results*."

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 Senior Vice President of Operations, 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.

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 other locations including New York, New York; and San Diego, California. 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.

Item 3. Legal Proceedings.

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse impact on our financial position, results of operations or cash flows. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors. Information pertaining to legal proceedings

is provided in Note 16, *Commitments and Contingencies – Legal Proceedings*, to our audited consolidated financial statements in included elsewhere in this Form 10-K and is incorporated herein by reference.

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 1, 2024, there were 91 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. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As of the completion of our corporate reorganization, under Dutch law, we may only pay dividends to the extent our shareholders' equity (eigen vermogen) exceeds the sum of the paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association and (if it concerns a distribution of profits) after adoption of the annual accounts by the 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

As previously disclosed, in November 2018 and October 2020, ATAI Life Sciences AG issued an aggregate principal amount of €1.0 million of convertible notes in a notional amount of €1.00 each (the "2018 Notes"), each such 2018 Note convertible into one common share of ATAI Life Sciences AG at a conversion price of €17.00 per common share (an "ATAI AG Conversion Share").

In connection with the 2018 Notes, on 21 July 2023, we entered into a Notes Conversion Agreement (the "Agreement") with ATAI Life Sciences AG and a noteholder. Pursuant to the Agreement, the noteholder intended to convert 995 of its 2018 Notes into ATAI AG Conversion Shares in exchange for an aggregate payment of €16,915. In addition, pursuant to the Agreement, concurrent with the conversion of the 2018 Notes into ATAI AG Conversion Shares, the ATAI AG Conversion Shares were exchanged on October 25, 2023 for 15,920 common shares, par value €0.10 per share, of the Company through a transfer and sale arrangement.

No underwriter or underwriting discount was involved in the issuance of the common shares of the Company. The Agreement and the common shares of the Company issued in connection with the above transactions were offered and sold in transactions that were exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

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.

Business Overview

We are a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. We were founded in 2018 in response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines to achieve clinically meaningful and sustained behavioral change in mental health patients.

We have a bold and ambitious vision: to heal mental health disorders so that everyone, everywhere can live a more fulfilled life.

Mental health disorders such as depression, substance use disorder, or SUD, and anxiety, which are among our initial focus indications, are highly prevalent and estimated to affect more than one billion people globally. In addition, the total costs of mental health disorders are significant and expected to increase substantially. 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 the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors, or SSRIs, and serotonin-norepinephrine reuptake inhibitors, or SNRIs, are well established and effective for certain patients, a significant percentage of patients either respond inadequately or relapse, translating to a significant unmet patient need.

Since our inception in 2018, we have focused substantially all of our efforts and financial resources on acquiring and developing product and technology rights, establishing our platform, building our intellectual property portfolio and conducting research and development activities for our product candidates within our atai companies that we consolidate based on our controlling financial interest of such entities. We operate a decentralized model to enable scalable drug or technological development at our atai companies. Our atai companies drive the development of our programs and enabling technologies for which we have either acquired a controlling or significant interest in or created de novo. We believe that this model provides our development teams the support and incentives to rapidly advance their therapeutic candidates or technologies in a cost-efficient manner. We look to optimize deployment of our capital in order to maximize value for our stakeholders.

We provide our development teams with access to shared services including scientific, intellectual property, clinical, and regulatory support, as well as project management, research and development, market strategy, and development and corporate finance. Our global team of subject matter professionals provides deep domain expertise in areas such as mental health drug development and life sciences intellectual property. Development teams have access to relevant expertise specific to each stage of their development. We believe our knowledge and specialization in psychedelics and mental health continuously enhance the quality of the services we provide through the sharing of learnings and experiences across the teams.

On June 22, 2021, we completed an IPO on Nasdaq, in which we issued and sold 17,250,000 common shares at a public offering price of $15.00 per share, including 2,250,000 common shares sold pursuant to the underwriters' exercise of their option to purchase additional common shares, for aggregate net proceeds of $231.6 million, after deducting underwriting discounts and commissions of $18.1 million and offering costs of $9.0 million. Prior to the IPO, we received gross cash proceeds of $361.5 million from sales of our common shares and convertible notes.

We have incurred significant operating losses since our inception. Our net loss attributable to ATAI Life Sciences N.V. stockholders was $40.2 million and $152.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, our accumulated deficit was $550.9 million and $510.2 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 at our atai companies that we consolidate based on our controlling financial interest of such entities as determined under the variable interest entity model ("VIE model") or voting interest entity model ("VOE model"). 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 incur additional 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 financings, 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.

As of December 31, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $109.2 million. Based on our current operating plan, we estimate that our existing cash, 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 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources—Liquidity Risk" below.

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.

Impactful 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 July 2022 through reduction of capital allocation and operational resources, we decided to decelerate some of our drug discovery programs and Revixia Life Sciences. In November 2022, we finalized and entered into agreements through which we disposed of our equity interests in (and residual Preferred Stock Purchase Agreement funding obligations to) Neuronasal, Inc. In late 2023, we finalized and entered into agreements through which we disposed of our equity interests in Psyber, Inc. and TryptageniX Inc. We are evaluating potential divestiture of our equity interests in certain other programs and also exploring other opportunities, including but not limited to seeking strategic partnership options, for example, with Recognify Life Sciences, Inc., Perception Neuroscience Holdings, Inc., and Kures, Inc.

In addition, in February 2023 we conducted a reduction in force of approximately 30% of our global workforce in February 2023 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.

Hercules Term Loan

On August 9, 2022, we entered into the Loan Agreement (as defined below) with Hercules Capital, Inc., which provided for a term loan facility for up to $175 million. Under the amended terms of the Loan Agreement, $15 million was drawn at closing, with an additional $10 million available to be drawn at our option by November 15, 2024, and, thereafter, an additional $15 million available to be drawn at our option by December 15, 2024. The remaining $135 million becomes available in tranches through March 31, 2025, subject to the satisfaction of certain conditions. For more information about the terms and conditions of the Loan Agreement, see Note 11 to our consolidated financial statements included in this Annual Report as well as "—Liquidity and Capital Resources—Indebtedness—Hercules Term Loan."

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, 2023 and 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 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. Since our inception, we have created wholly owned subsidiaries or made investments in certain controlled entities, including partially-owned subsidiaries for which we have majority voting interest under the VOE model or for which we are the primary beneficiary under the VIE model, which we refer to collectively as its consolidated entities. 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 income (loss) attributable to the noncontrolling interests is presented as net income (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 as cost and equity method investments. If we have not elected the fair value option, we then 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 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 we elected the fair value option, the fair value of the investments will be recorded upon acquisition and any changes in fair value will be recorded 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.

For the foreseeable future, we may generate revenue from reimbursements of services under the Otsuka Agreement, as well as milestone payments under our current and/or future collaboration agreements. 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 lab 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 nonrefundable 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.

Acquisition of in-process research and development expenses

Acquisition of in-process research and development ("IPR&D") expenses consist of acquired IPR&D with no future alternative use based on the probability of clinical success.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including 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 and facility-related expenses, advertising, and information technology-related expenses.

Other income, 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 our 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, or RDTI, program. 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, 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, convertible promissory notes and derivative liability, and warrant 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 investment held at fair value consists of subsequent remeasurements of our investments held at fair value, including COMPASS Pathways plc ("COMPASS") and IntelGenx Technologies Corp. ("IntelGenx") for which we have elected the fair value option.

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 have elected the fair value option.

Change in fair value of contingent consideration liability - related parties

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

Change in fair value of contingent consideration liability

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

Change in the 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.

Change in fair value of warrant liability

Change in fair value of warrant liability consists of subsequent remeasurements of our warrant liability relating to issued and outstanding warrants to purchase shares of Neuronasal, Inc. ("Neuronasal") common stock acquired in connection with the acquisition of Neuronasal in May 2021. We deconsolidated Neuronasal in November 2022.

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, including DemeRx NB, Inc. ("DemeRx NB").

Gain on deconsolidation of a variable interest entity

Gain on deconsolidation of a variable interest entity is the result of removing assets and liabilities from our consolidated balance sheet following a loss of control or divestment 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 expense, net

Other income consists principally of the impact of accounting adoptions and changes in the carrying values of our assets and liabilities.

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, 2023. In assessing the realizability on deferred tax assets, we consider whether it is more-likely-than-not that some or all of 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 as of December 31, 2023 and December 31, 2022 are $0.4 million and $0, respectively, which represent the amounts that, if recognized, impact the effective income tax rate in future periods. We accrued $0.1 million and $0 for interest and penalties as of December 31, 2023 and December 31, 2022, 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, 2023 and 2022

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands, except percentages)			
License revenue	$ 314	$ 233	$ 81	34.8 %
Operating expenses:				
Research and development	62,203	74,313	(12,110)	(16.3 %)
Acquisition of in-process research and development	—	357	(357)	(100.0 %)
General and administrative	63,582	70,350	(6,768)	(9.6 %)
Total operating expenses	125,785	145,020	(19,235)	(13.3 %)
Loss from operations	(125,471)	(144,787)	19,316	(13.3 %)
Other income, net:				
Interest income	1,847	548	1,299	237.0 %
Interest expense	(2,656)	(923)	(1,733)	187.6 %
Benefit from research and development tax credit	2,445	—	2,445	0.0 %
Change in fair value of assets and liabilities, net	86,583	2,083	84,500	4056.6 %
Impairment of other investments	(1,011)	—	(1,011)	0.0 %
Gain on deconsolidation of a variable interest entity, net	60	1,484	(1,424)	(96.0 %)
Foreign exchange gain (loss), net	(894)	6,902	(7,796)	(112.9 %)
Other expense, net	(189)	(489)	300	(61.3 %)
Total other income, net	86,185	9,605	76,580	797.3 %
Loss before income taxes	(39,286)	(135,182)	95,896	(70.9 %)
Provision for income taxes	(1,016)	(6,229)	5,213	(83.7 %)
Losses from investments in equity method investees, net of tax	(3,593)	(16,006)	12,413	(77.6 %)
Net loss	$ (43,895)	$ (157,417)	$ 113,522	(72.1 %)
Net loss attributable to noncontrolling interests	(3,671)	(5,032)	1,361	(27.0 %)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (40,224)	$ (152,385)	$ 112,161	(73.6 %)

License revenue

License revenue was $0.3 million and $0.2 million for the years ended December 31, 2023, and 2022, respectively, which related to reimbursement of research and development expenses under the Otsuka Agreement. For the years ended December 31, 2023, and 2022, respectively, there were no milestones achieved under the Otsuka Agreement.

Research and development expenses

The table and discussion below present research and development expenses for the years ended December 31, 2023 and 2022:

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands, except percentages)			
Direct research and development expenses by program:				
Psychedelic Programs				
VLS-01	$ 9,055	$ 4,206	$ 4,849	115.3 %
IBX-210 & DMX-1002	1,639	3,495	(1,856)	(53.1 %)
EMP-01	2,635	4,365	(1,730)	(39.6 %)
EGX-A & EGX-B	2,238	1,594	644	40.4 %
Non-psychedelic Programs				
RL-007	9,154	3,586	5,568	155.3 %
Other Programs				
PCN-101	5,753	14,206	(8,453)	(59.5 %)
KUR-101	217	3,347	(3,130)	(93.5 %)
RLS-01	136	2,026	(1,890)	(93.3 %)
Enabling Technologies and Drug Discovery Platforms	3,099	7,180	(4,081)	(56.8 %)
Unallocated research and development expenses:				
Personnel expenses	25,656	28,716	(3,060)	(10.7 %)
Professional and consulting services	1,952	1,006	946	94.0 %
Other	669	588	81	13.8 %
Total research and development expenses	$ 62,203	$ 74,313	$ (12,110)	(16.3 %)

Research and development expenses were $62.2 million for the year ended December 31, 2023, compared to $74.3 million for the year ended December 31, 2022. The decrease of $12.1 million was primarily attributable to a decrease of $10.1 million of direct costs in our programs as discussed below, a $3.0 million decrease in personnel expenses (inclusive of a $3.5 million decrease in stock-based compensation and $1.9 million increase in restructuring charges), a $0.9 million increase in professional and consulting fees, and a $0.1 million increase in other expenses.

Psychedelic Programs

VLS-01: N,N-dimethyltryptamine; ("DMT") for Treatment Resistant Depression

The $4.8 million increase in direct costs for our VLS-01 program was primarily due to an increase of $1.9 million of clinical development costs, $1.7 million of preclinical development costs, and an increase of $1.2 million of manufacturing costs relating to our Phase 1 three-part trial and Phase 1b trial of VLS-01 designed to evaluate the safety, tolerability, PK and PD of VLS-01 delivered by intravenous (IV) infusion and using our proprietary oral transmucosal film (OTF) formulation.

IBX-210 & DMX-1002: Ibogaine for Opioid Use Disorder

The $1.9 million decrease in direct costs for our DMX-1002 program was primarily due to a decrease of $1.7 million of clinical development costs, a decrease of $0.1 million of manufacturing costs, and a decrease of $0.1 million of personnel and other related costs for the conduct of our Phase 1/2 trial to evaluate its safety, tolerability, PK, and efficacy in recreational drug users and healthy volunteers.

EMP-01: 3,4-methylenedioxy-methamphetamine (MDMA) derivative for Post Traumatic Stress Disorder

The $1.7 million decrease in direct costs for our EMP-01 program was primarily due to a decrease of $2.5 million preclinical development costs and a $0.7 million decrease of manufacturing costs, partially offset by an increase of $1.5 million in clinical development costs relating to our Phase 1 single ascending dose trial to assess the safety and tolerability of orally administered EMP-01.

EGX-A & EGX-B: Novel 5-HT2A Receptor Agonists

The $0.6 million increase in direct costs for EGX-A & EGX-B was primarily due to an increase in $0.6 million of preclinical development costs.

Non-psychedelic Programs

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

The $5.6 million increase in direct costs for our RL-007 program was primarily due to an increase of $5.6 million of clinical development costs relating to our Phase 2b proof-of-concept clinical trial for RL-007 in CIAS.

Other Programs

PCN-101 (R-Ketamine) for Treatment Resistant Depression

The $8.5 million decrease in direct costs for our PCN-101 program was primarily due to a decrease of $5.6 million of clinical development costs, $1.4 million of manufacturing costs, $1.0 million of preclinical development costs, and $0.5 million of personnel costs.

KUR-101 (deuterated mitragynine) for Opioid Use Disorder

The $3.1 million decrease in direct costs for our KUR-101 program was primarily due to a $2.2 million decrease of clinical development costs, $0.7 million decrease of preclinical development costs, $0.1 million decrease in manufacturing costs, and $0.1 million decrease in personnel costs.

RLS-01 for Treatment Resistant Depression

The $1.9 million decrease in direct costs for our RLS-01 program was primarily due to a decrease of $1.2 million of manufacturing costs and $0.7 million of preclinical development costs.

Enabling Technologies and Drug Discovery Platforms

The $4.1 million decrease in our enabling technologies and drug discovery platforms primarily relates to decreased direct costs of $1.4 million in our Invyxis program, $1.2 million in our TryptageniX program, $0.9 million in our InnarisBio program, $0.3 million in our PsyProtix program, and $0.3 million in our Introspect program.

Acquisition of in-process research and development expense

We did not incur any acquisition of in-process research and development expenses for the year ended December 31, 2023. Acquisition of in-process research and development expenses was $0.4 million for the year ended December 31, 2022, which related to license costs incurred by our KUR-101 program.

General and administrative expenses

General and administrative expenses were $63.6 million for the year ended December 31, 2023 compared to $70.4 million for the year ended December 31, 2022. The decrease of $6.8 million was primarily related to a $8.1 million decrease in personnel expenses (inclusive of a $5.9 million decrease in stock-based compensation, a $1.4 million increase in restructuring expenses), a $1.8 million decrease in investor relations and public company compliance expenses, and a $1.8 million decrease in insurance expenses; partially offset by an increase of $3.3 million in non-income tax expense and a $1.6 million increase in professional consulting services.

Subsequent to our February 2023 reductions in force, 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, net

Interest income

Interest income for the years ended December 31, 2023 and 2022 was $1.8 million and $0.5 million, respectively. Interest income earned on cash balances increased $1.1 million as a result of higher balances in interest bearing accounts. Interest income earned on the IntelGenx note receivable increased $0.2 million due to the $3.0 million loan tranche paid to IntelGenx in January 2023.

Interest expense

Interest expense was $2.7 million and $0.9 million for the years ended December 31, 2023 and 2022, respectfully, which consists primarily of interest expense incurred in connection with our 2022 Term Loan Facility with Hercules Capital, Inc., which was entered into in August 2022.

Benefit from research and development tax credit

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. We recognized an immaterial research and development tax credit for the year ended December 31, 2022.

Change in fair value of assets and liabilities, net:

Change in fair value of securities held at fair value

During the years ended December 31, 2023 and 2022,, we recognized a gain of $5.4 million and $0.3 million, respectively, relating to the change in fair value of our available for sale securities.

Change in fair value of other investments held at fair value

During the year ended December 31, 2023, we recognized a $81.9 million change in fair value relating to our COMPASS investment, resulting from an accounting method change in which we elected the fair value option following our loss of significant influence, as well as an immaterial change in the fair value of our IntelGenx investment.

Change in fair value of convertible notes receivable - related party

During the year ended December 31, 2023, we recognized a change of $0.1 million in the fair value of our convertible notes receivable with IntelGenx, which were acquired in 2023.

*Change in fair value of contingent consideration liability—related partie*s

The milestone and royalty payments in relation to the acquisition of Perception and InnarisBio were recorded at the acquisition date, and are subsequently remeasured to fair value. We recorded an immaterial gain for the year ended December 31, 2023 compared to a $1.5 million gain for the year ended December 31, 2022. The change in fair value of our contingent consideration liability was primarily attributable to updates to certain estimated assumptions in relation to Perception.

Change in fair value of contingent consideration liability

In October 2023, we acquired the noncontrolling interest's shares 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 is recorded at fair value at the transaction date and subsequently remeasured at fair value. As of the year ended December 31, 2023, we recorded a $0.1 million loss related to the DemeRx IB contingent consideration change in fair value. In December 2023, we disposed of our equity interest in TryptageniX, but retained the contingent consideration liability, which is subsequently remeasured to fair value. As of the year ended December 31, 2023, we recorded an immaterial gain related to the TryptageniX contingent consideration.

Change in fair value of convertible promissory notes

In December 2023, certain 2020 convertible noteholders exchanged the 2020 convertible notes issued by ATAI Life Sciences AG for notes issued by ATAI Life Sciences N.V., which are convertible into ATAI NV common shares. The notes issued by ATAI Life Sciences N.V. contain an embedded derivative that required bifurcation. This embedded derivative is valued quarterly. For the year ended December 31, 2023, we recognized a $0.7 million loss due to a change in the fair value of the conversion option of the notes issued by ATAI Life Sciences N.V.

Change in fair value of warrant liability

In connection with the November 2022 divestment of our equity interest in Neuronasal, we remeasured the Neuronasal warrant liability to have a $0.3 million fair value immediately prior to the divestment. The fair value of the Neuronasal warrant liability was determined to be de minimis at divestment. For the year ended December 31, 2022, we recorded a gain of $0.3 million related to the change in fair value of the Neuronasal warrant liability attributed to the divestment of Neuronasal.

Impairment of other investments

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

Gain on deconsolidation of a variable interest entity was $0.1 million for the year ended December 31, 2023 as a result of the gain upon deconsolidation of Trypotagenix of $0.4 million, partially offset by the loss upon deconsolidation of Psyber, Inc. of $0.3 million, compared to a gain of $1.5 million for the year ended December 31, 2022 as a result of the deconsolidation of Neuronasal.

Foreign exchange gain (loss), net

Foreign exchange loss was $0.9 million for the year ended December 31, 2023 compared to a $6.9 million gain for the year ended December 31, 2022 relating 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 expense, net

Other expense, net for the year ended December 31, 2023 was $0.2 million, which primarily related to our write-off of certain receivables. Other expenses, net for the year ended December 31, 2022 of $0.5 million was primarily related to the recognition of an allowance for the Neuronasal note receivable in connection with the Neuronasal divestment.

Provision for income taxes

We incurred current income tax expense of $1.0 million and a deferred income tax expense of $0.0 million for the year ended December 31, 2023. We incurred current income tax expense of $1.1 million and a deferred income tax benefit of $5.1 million for the year ended December 31, 2022. Our current income tax expense relates to book profits and thus taxable profits generated in one of our United States subsidiaries, our United Kingdom subsidiary, and one of our Australian subsidiaries. The deferred income tax expense relates to certain deferred tax assets being offset by a valuation allowance in the year ended December 31, 2023 primarily with regard to temporary timing difference arising in connection with stock-based compensation expense.

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, 2023 and 2022 were $3.6 million and $16.0 million, respectively. We recorded a $10.1 million loss in 2022 related to our COMPASS investment, which reduced the investment carrying value to zero. No further loss was recorded in 2023. The loss related to our GABA Therapeutics, Inc investment decreased by $2.3 million year-over-year.

Net loss attributable to noncontrolling interests

Net losses attributable to noncontrolling interests for the years ended December 31, 2023 and 2022 were $3.7 million and $5.0 million, respectively which relate to the noncontrolling interests in Recognify, Perception, and Kures.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2023 and 2022, we had net losses attributable to ATAI Life Sciences N.V. shareholders of $40.2 million and $152.4 million, respectively. As of December 31, 2023 and 2022, our accumulated deficit was $550.9 million and $510.2 million, respectively. We expect to continue to incur losses and operating cash outflows for the foreseeable future until we are able to commercialize any of our product candidates. Our primary sources of liquidity are our cash and cash equivalents, short-term securities,

convertible promissory notes, investments, and 2022 Term Loan Facility, as further described below. We maintain cash balances with financial institutions in excess of insured limits.

Sources of Liquidity

Initial Public Offering

In June 2021, we completed our IPO and issued and sold 17,250,000 common shares at a price to the public of $15.00 per share, which included the exercise in full by the underwriters of their option to purchase 2,250,000 additional common shares. We received aggregate net proceeds of $231.6 million, after underwriting discounts and commissions of $18.1 million and offering costs of $9.0 million. As of December 31, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $109.2 million. Prior to the IPO, we received gross cash proceeds of $361.5 million from sales of our common shares and convertible notes.

As of December 31, 2023, we had $154.2 million in cash and cash equivalents and short-term investment securities.

Convertible Promissory Notes

In November 2018, we issued an aggregate principal amount of $0.2 million of convertible notes ("2018 Convertible Notes"). The 2018 Convertible Notes are non-interest-bearing and have a maturity date of September 30, 2025, unless previously redeemed, converted, purchased or cancelled. In October 2020, we issued an additional principal amount of $1.0 million of the 2018 Convertible Notes. 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.

From 2021 through December 31, 2023, certain noteholders elected to convert their 2018 Convertible Notes into shares of ATAI Life Sciences N.V. These investors each paid €17.00 per share for an aggregate amount of €10.4 million ($12.2 million) in order to convert their respective 2018 Convertible Notes into ATAI Life Sciences AG common shares.

In December 2023, a 2018 Convertible Notes holder entered into an agreement with ATAI Life Sciences N.V. to exchange its 2018 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, 2023 the 2018 Convertible Notes had a principal balance of $0.2 million and the new ATAI Life Sciences N.V. notes had a principal balance of $0.2 million. If all convertible notes were converted, the Company would receive proceeds of €6.6 million ($7.3 million).

Investments

A significant potential source of liquidity resides in our investment in COMPASS's American Depositary shares, subject to market conditions. Based on quoted market prices, the market value of our ownership in COMPASS was $83.7 million as of December 31, 2023. As of December 31, 2023, our ownership percentage in COMPASS was 15.4%.

Hercules Term Loan

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

Liquidity Risks

As of December 31, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $109.2 million. Based on our current operating plan, we estimate that our existing cash, 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 2026.

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, 2023 and 2022:

	December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (84,118)	$ (104,467)
Net cash used in investing activities	(53,295)	(86,848)
Net cash provided by financing activities	(8,355)	20,785
Effect of foreign exchange rate changes on cash	189	(1,123)
Net increase (decrease) in cash	$ (145,579)	$ (171,653)

Net Cash Used in Operating Activities

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 investment, $0.8 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 was primarily due to a $8.7 million decrease in prepaid expenses and a $2.1 million increase in accounts payable, partially offset by a $3.3 million decrease in accrued liabilities.

Net cash used in operating activities was $104.5 million for the year ended December 31, 2022, which consisted of a net loss attributable to stockholders of $157.4 million, adjusted by noncash charges of $56.3 million and net cash outflows from the change in operating assets and liabilities of $3.3 million. The noncash charges primarily consisted of $42.4 million of stock-based compensation, $16.0 million of losses from our equity method investments, $5.1 million of deferred tax provision expense, $0.9 million impairment of loan receivable and $0.4 million of IPR&D considered to have no future alternative use, partially offset by $5.0 million of unrealized foreign exchange gains, $1.5 million gain on deconsolidation of a variable interest entity and $1.5 million gain from the change in fair value of contingent consideration liabilities. The net cash outflows from the change in operating assets and liabilities were primarily due to a $3.0 million decrease in accounts payable and a $1.5 million increase in prepaid expenses, partially offset by a $1.2 million increase in accrued liabilities.

Net Cash Used in Investing Activities

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, $25.0 million of cash committed in anticipation of the closing of Beckley Psytech investment in January 2024, $3.5 million of loans remitted to related party, $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 used in investing activities was $86.8 million for the year ended December 31, 2022, primarily driven by $309.1 million of cash paid for securities carried at fair value, $3.0 million of loans remitted to related parties, additional investments of $0.6 million in our other investments, $0.8 million of purchases of property and equipment, and $0.3 million of capitalized internal-use software development costs, partially offset by $226.8 million of proceeds from sale and maturities of securities at fair value.

Net Cash Provided by Financing Activities

Net cash used by financing activities of $8.4 million for the year ended December 31, 2023 consisted of $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.

Net cash provided by financing activities was $20.8 million for the year ended December 31, 2022, primarily due to $15 million of proceeds from debt financings, $4.6 million of proceeds from conversion of convertible notes to common shares, $2.3 million of proceeds from stock option exercises and $0.6 million of proceeds from issuance of subsidiary preferred shares, partially offset by $1.7 million of debt financing costs paid.

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 Convertible Notes. The 2018 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. The noteholders have agreed to, 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.

From 2021 through December 31, 2023, certain noteholders elected to convert their 2018 Convertible Notes into shares of ATAI Life Sciences N.V. These investors each paid €17.00 per share for an aggregate amount of €10.4 million ($12.2 million) in order to convert their respective 2018 Convertible Notes into ATAI Life Sciences AG common shares. which was in accordance with the original terms of the 2018 Convertible Note Agreements. Concurrent with the conversion of the 2018 Convertible Notes into common shares of ATAI Life Sciences AG, the common shares of ATAI Life Sciences AG that were issued to the noteholders were exchanged for 5,478,176 shares of ATAI Life Sciences N.V. through a transfer and sale arrangement such that ATAI Life Sciences AG continued to remain a wholly owned subsidiary of ATAI Life Sciences N.V and the transaction was accounted for as an equity transaction that resulted in no gain or loss recognition.

In December 2023, a 2018 Convertible Notes holder entered into an agreement with ATAI Life Sciences N.V. to exchange its 2018 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, 2023 the 2018 Convertible Notes had a principal balance of $0.2 million and the new ATAI Life Sciences N.V. notes had a principal balance of $0.2 million.

Hercules Term Loan

On August 9, 2022 (the "Closing Date"), we, ATAI Life Sciences AG ("ATAI AG" and together with the Company, the "Borrowers") and certain of our subsidiary guarantors (collectively, the "Subsidiary Guarantors") entered into a Loan and Security Agreement (the "2022 Term Loan Facility") with Hercules Capital, Inc. ("Hercules"), in its capacity as administrative agent and collateral agent (the "Agent") and as a lender, and certain other financial institutions that from time to time become parties to the Loan Agreement, as defined below, as lenders (collectively, the "Lenders"). The Loan Agreement provides for term loans in an aggregate principal amount of up to $175.0 million under multiple tranches.

On May 26, 2023, the "Company, ATAI Life Sciences N.V., ATAI Life Sciences AG ("ATAI AG" and together with the Company, the "Borrowers") and certain of our subsidiary guarantors of the Company (collectively, the "Subsidiary Guarantors") entered into the Second Amendment to Loan and Security Agreement (the "Second Amendment"), with the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, the "Lenders") and Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and for the Lenders (the "Agent") which amends that certain Loan and Security Agreement, dated August 9, 2022 (as amended by that certain First Amendment to Loan and Security Agreement dated as of March 13, 2023, the "Existing Loan Agreement" and as amended by the Second Amendment, the "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 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 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.

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 achieve certain performance milestones, raise at least $175.0 million of unrestricted new net cash proceeds from certain permitted sources after the Closing Date and prior to December 15, 2024, and satisfy certain other specified conditions. The outstanding principal balance of the Loan Agreement 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 4.55% and (ii) 8.55%. 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, for a period of thirty (30) months following the Closing Date, which period may be extended to (i) thirty-six months if certain additional performance milestones have been achieved; and (ii) forty-two months if certain additional performance milestones have been 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 Loan Agreement.

The 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 Loan Agreement requires that beginning on the later of (i) July 1, 2023 and (ii) the date on which the aggregate outstanding amount borrowed under the 2022 Term Loan Facility is equal to or greater than $40.0 million, we shall maintain Qualified Cash in an amount no less than the sum of (1) 33% of the outstanding amount under the Loan Agreement, 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, 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, 2023 we were in compliance with all applicable covenants under the 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 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 sheet as of December 31, 2023, 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 10.*Leases*, Note 16. C*ommitments and Contingencies*, and Note 17. *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 16 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.

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 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 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 year ended December 31, 2023 we made no 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 year ended December 31, 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, 2022.

During the year ended December 31, 2023, we made no 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. 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, 2023 and 2022, we recorded $2.0 million and $2.8 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.

Licenses of Intellectual Property

We may 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. The agreements may have units of account within the scope of Accounting Standards Codification ("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 our intellectual property or sale of our 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.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its collaboration and license agreements, we perform the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are capable of being distinct and distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements we must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above; and d) the measure of progress in step (v) above. We use 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 our intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize 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, we consider 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, we consider 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, we utilize 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. We evaluate 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 we record in future periods.

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 years ended December 31, 2023 and 2022, 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, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $109.2 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 investment grade marketable debt securities 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, 2023, we had $0.4 million in convertible promissory notes, which was comprised of non-interest-bearing borrowings under the 2018 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.

As of December 31, 2023, the carrying amount of our short and long-term notes receivables was an aggregate amount of $11.8 million. Based on the principal amounts of the notes receivable and the interest rates assigned to each note receivable as per their respective contracts, an immediate 10% change in the interest rates would not have a material impact on our notes receivables, 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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These 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 28, 2024

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,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 45,034	$ 190,613
Securities carried at fair value	109,223	82,496
Committed Investment Funds	25,000	—
Prepaid expenses and other current assets	5,830	14,036
Short term notes receivable - related party, net	505	—
Total current assets	185,592	287,145
Property and equipment, net	981	928
Operating lease right-of-use asset, net	1,223	226
Other investments held at fair value	89,825	—
Other investments	1,838	6,755
Long term notes receivable - related parties, net	97	7,262
Convertible notes receivable - related party	11,202	—
Other assets	2,720	3,125
Total assets	$ 293,478	$ 305,441
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,589	$ 2,399
Accrued liabilities	15,256	17,306
Current portion of lease liability	275	180
Other current liabilities	—	12
Total current liabilities	20,120	19,897
Contingent consideration liability - related parties	620	953
Contingent consideration liability	1,637	—
Noncurrent portion of lease liability	990	44
Convertible promissory notes - related parties	164	415
Convertible promissory notes and derivative liability	2,666	—
Long term debt, net	15,047	14,702
Other liabilities	7,918	3,664
Total liabilities	$ 49,162	$ 39,675
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, €0.10 par value ($0.12 par value at December 31, 2023 and 2022); 750,000,000 shares authorized at December 31, 2023 and 2022; 166,026,396 and 165,935,914 shares issued and outstanding at December 31, 2023 and 2022, respectively	18,573	18,562
Additional paid-in capital	794,787	774,092
Share subscription receivable	—	(24)
Accumulated other comprehensive loss	(19,460)	(21,702)
Accumulated deficit	(550,938)	(510,188)
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	242,962	260,740
Noncontrolling interests	1,354	5,026
Total stockholders' equity	244,316	265,766
Total liabilities and stockholders' equity	$ 293,478	$ 305,441

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)

	Years Ended December 31,	
	2023	2022
License revenue	$ 314	$ 233
Operating expenses:		
Research and development	62,203	74,313
Acquisition of in-process research and development	—	357
General and administrative	63,582	70,350
Total operating expenses	125,785	145,020
Loss from operations	(125,471)	(144,787)
Other income, net:		
Interest income	1,847	548
Interest expense	(2,656)	(923)
Benefit from research and development tax credit	2,445	—
Change in fair value of assets and liabilities, net	86,583	2,083
Impairment of other investments	(1,011)	—
Gain on deconsolidation of a variable interest entity, net	60	1,484
Foreign exchange gain (loss), net	(894)	6,902
Other expense, net	(189)	(489)
Total other income, net	86,185	9,605
Loss before income taxes	(39,286)	(135,182)
Provision for income taxes	(1,016)	(6,229)
Losses from investments in equity method investees, net of tax	(3,593)	(16,006)
Net loss	(43,895)	(157,417)
Net loss attributable to noncontrolling interests	(3,671)	(5,032)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (40,224)	$ (152,385)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.25)	$ (0.98)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	158,833,785	155,719,585

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31, 2023	2022
Net loss	$ (43,895)	$ (157,417)
Other comprehensive income (loss):		
Foreign currency translation adjustments, net of tax	2,242	(13,366)
Comprehensive loss	$ (41,653)	$ (170,783)
Net loss attributable to noncontrolling interests	(3,671)	(5,032)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests	(1)	50
Comprehensive loss attributable to noncontrolling interests	(3,672)	(4,982)
Comprehensive loss attributable to ATAI Life Sciences N.V. stockholders	$ (37,981)	$ (165,801)

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 Paid-In Capital	Share Subscriptions Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity Attributable to ATAI Life Sciences N.V. Stockholders	Noncontrolling Interests	Total Stockholders' Equity
	Shares	Amount							
Balances at December 31, 2021	160,677,001	$ 18,002	$ 725,045	$ —	$ (8,336)	$ (357,803)	$ 376,908	$ 9,051	$ 385,959
Issuance of subsidiary preferred shares	—	—	—	—	—	—	—	600	600
Issuance of subsidiary common shares	—	—	—	—	—	—	—	357	357
Conversion of convertible notes to common stock	4,320,000	447	4,466	—	—	—	4,913	—	4,913
Issuance of shares upon exercise of stock options	938,913	113	2,206	(24)	—	—	2,295	—	2,295
Stock-based compensation expense	—	—	42,375	—	—	—	42,375	—	42,375
Foreign currency translation adjustment, net of tax	—	—	—	—	(13,366)	—	(13,366)	50	(13,316)
Net loss	—	—	—	—	—	(152,385)	(152,385)	(5,032)	(157,417)
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 note conversion	15,920	2	18	—	—	—	20	—	20
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
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

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (43,895)	$ (157,417)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of long term assets	319	168
Noncash lease expense	383	—
Amortization of debt discount	371	131
In-process research and development expense	—	357
Stock-based compensation expense	32,982	42,375
Change in the fair value of assets and liabilities, net	(86,583)	(2,083)
Impairment of other investments	1,011	—
Gain on deconsolidation of a variable interest entity, net	(60)	(1,484)
Impairment of short term note receivable	—	852
Provision for deferred income taxes	—	5,074
Unrealized foreign exchange gain (loss)	799	(4,950)
Losses from investments in equity method investees, net of tax	3,593	16,006
Other	(507)	(161)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	8,663	(1,522)
Accounts payable	2,138	(3,034)
Accrued liabilities	(3,332)	1,221
Net cash used in operating activities	(84,118)	(104,467)
Cash flows from investing activities		
Cash paid for securities carried at fair value	(160,262)	(309,058)
Proceeds from sale and maturities of securities carried at fair value	138,983	226,834
Funds committed for investments	(25,000)	—
Cash paid for property and equipment	(259)	(773)
Cash paid for capitalized internal-use software development costs	(331)	(251)
Cash paid for other investments held at fair value	(956)	—
Cash paid for other investments	—	(600)
Proceeds from sale of other investments	486	—
Cash paid for long term notes receivable - related parties	(3,500)	(3,000)
Cash paid for convertible notes receivable - related party	(2,014)	—
Cash paid out in variable interest entity deconsolidation	(443)	—
Net cash used in investing activities	(53,295)	(86,848)
Cash flows from financing activities		
Proceeds from issuance of subsidiary preferred shares	—	600
Cash paid for acquisition of noncontrolling interest	(8,480)	—
Proceeds from conversion of convertible notes to common stock	20	4,636
Proceeds from issuance of shares upon exercise of stock options	205	2,294
Proceeds from debt financings	—	15,000
Cash paid for debt financing	(100)	(1,745)
Net cash provided by financing activities	(8,355)	20,785
Effect of foreign exchange rate changes on cash	189	(1,123)
Net decrease in cash and cash equivalents	(145,578)	(171,653)
Cash and cash equivalents – beginning of the period	190,613	362,266
Cash and cash equivalents – end of the period	$ 45,034	$ 190,613
Supplemental disclosures:		
Cash paid for interest	$ 1,923	$ 508
Cash paid for taxes	$ 1,475	$ 652
Supplemental disclosures of non cash investing and financing information:		
Noncash consideration for acquisition of noncontrolling interest, net	$ 2,315	$ —
Noncash exchange of convertible promissory note modification	$ 1,668	$ —
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	$ 487
Issuance of subsidiary shares to noncontrolling interests in connection with Columbia stock purchase agreement	$ —	$ 357
Share subscription receivable	$ —	$ 24

See accompanying notes to the consolidated financial statements.

1. Nature 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. atai was founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape and is dedicated to efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines to achieve clinically meaningful and sustained behavioral change in mental health patients.

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, 2023, the Company had cash and cash equivalents of $45.0 million, short-term securities of $109.2 million and its accumulated deficit was $550.9 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.

The Company operates and manages the business as one reporting and one operating segment, which is the business of identifying and advancing mental health innovations. The Company has determined that its chief executive officer is the chief operating decision maker (“CODM”). The CODM reviews consolidated operating results to make decisions about allocating resources or capital to specific compounds or projects in line with overall Company’s strategies and goals. The Company operates in two geographic regions primarily in the United States and Germany.

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 operating right-of-use asset, related lease liability, and debt facility related interest 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. Since its inception, the Company has created wholly owned subsidiaries or made investments in certain controlled entities, including partially-owned subsidiaries for which it has majority voting interest under the VOE model or for which it is the primary beneficiary under the VIE model, which it refers to collectively as its consolidated entities. 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 income (loss)

attributable to the noncontrolling interests is presented as net income (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 as cost and equity method investments. If the company has not elected the fair value option, the Company then 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, the fair value of the investments 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, accruals for research and development costs, the fair value of contingent consideration liabilities, in-process research and development assets ("IPRD"), noncontrolling interests recognized in acquisitions, and the valuation of stock-based awards.

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, short-term investments, and all notes receivables. 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 credit risk associated with the Company's investment in all notes receivables is monitored and assessed periodically. 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, 2023 and 2022, 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, U.S. treasury securities, commercial paper, corporate notes/bonds, and U.S. government agencies securities. 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.

Property and Equipment

Property and equipment, consisting primarily of furniture and fixtures and leasehold improvements, 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. The company estimates the useful life of furniture and fixtures to be 7 years. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter.

Operating lease right-of-use asset

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.

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.

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").

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.

Acquisitions

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. During the years ended December 31, 2023 and 2022, the Company 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 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 in-process research and development ("IPR&D") with no alternative future use is charged to operating expenses at the acquisition date.

Other Investments Held at Fair Value

As permitted under Accounting Standards Codification 825, Financial Instruments, or ASC 825, the Company has elected the fair value option to account for its investment in IntelGenx, which otherwise would be subject to ASC 323. In accordance with ASC 825, the Company records this investment at fair value under the Other investments held at fair value in the Company's consolidated balance sheets and changes in fair value are recognized asChange in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations.

At the most recent remeasurement date, the Company evaluated its ability to continue to exercise significant influence over its investment and determined that it no longer had significant influence. The Company's COMPASS investment is accounted for at fair value under 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.

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 statement of operations.

Other Investments

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.

Convertible Notes Receivable

As permitted under ASC 825, *Financial Instruments*, or ASC 825, the Company has elected the fair value option to account for its IntelGenx convertible notes, which otherwise would be subject to ASC 320. In accordance with ASC 825, the Company records 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

The Company has certain notes receivable that are carried at cost, which includes the principal value of the note receivable, accrued interest and net of any payments received and expected credit losses. Management 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).

Based on the terms of the notes receivable, certain notes receivable are classified as long term as their payments are due after twelve months from the balance sheet date.

Contingent Consideration Liability

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 liability on the consolidated balance sheet. 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 sheet 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.

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.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its collaboration and license agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are capable of being distinct and distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above; and d) the measure of progress in step (v) above. 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 money market funds, funds held in trust, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature. The COMPASS investment is a Level 1 asset as its quoted price can be found on the Nasdaq market. The carrying amounts of investment securities and IntelGenx common stock are determined according to Level 2 inputs in the fair value hierarchy above. The

Company's investment in IntelGenx Warrants and Call Option Units, IntelGenx convertible notes receivable, and various contingent consideration liabilities are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above.

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.

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.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the Financial Accounting Standard Board ("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 is not early adopting the standard. We are currently evaluating this guidance to determine its impact on our consolidated financial statements.

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. We are currently evaluating this guidance to determine its impact on our consolidated financial statements.

3. Dispositions

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 sheet 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, net in the consolidated statement 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 sheet, 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 statement 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.

2022 Dispositions

Neuronasal, Inc.

In November 2022, the Company finalized and entered into a Redemption, Termination and Release Agreement ("Termination Agreement") with Neuronasal through which atai disposed of its equity interests and residual SPA funding obligations. Pursuant to the Neuronasal Termination Agreement, the Company transferred all of its approximately equity interest in Neuronasal in exchange for the redemption consideration in the form of certain warrants. The Neuronasal Termination Agreement entitles the Company to purchase certain common stock in Neuronasal upon the occurrence of certain contingencies, such as an initial public offering, qualified financing event, or certain clinical studies. The Company has no further obligations to fund Neuronasal.

As a result of the disposition, the Company ceased having controlling financial interest in Neuronasal. The Company determined that it was no longer the primary beneficiary, as it no longer had the power to direct the significant activities of Neuronasal, and accordingly

deconsolidated Neuronasal. Upon the effective termination date, the Company derecognized all of Neuronasal's assets and liabilities from its balance sheet, and recognized a gain of $1.5 million, which was reported as Gain on deconsolidation of a variable interest entity, a component of other income, net in the consolidated statement of operations for the year ended December 31, 2022. The Company determined that the value of the warrants received in connection with the Termination Agreement were de minimis as of the termination date and continue to be de minimis as of the year ended December 31, 2023. In connection with the deconsolidation of Neuronasal, the Company concluded that the loan assets were impaired and recognized an impairment of $0.9 million, which was reported in Other income(expense), net in the consolidated statements of operations for the year ended December 31, 2022

The Company concluded that the decision to deconsolidate Neuronasal, which was based on clinical data that did not meet expectations, did not represent a significant strategic shift. Therefore, the Company did not present the results of Neuronasal prior to deconsolidation as discontinued operations in its consolidated statements of operations for the year ended December 31, 2022.

4. Variable Interest Entities and a Voting Interest Entity

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, 2023.

As of December 31, 2023 and 2022, the Company has accounted for the following consolidated investments as VIEs, excluding the wholly owned subsidiaries:

Consolidated Entities	Relationship as of December 31, 2023	Relationship as of December 31, 2022	Date Control Obtained	Ownership % December 31, 2023	Ownership % December 31, 2022
Perception Neuroscience Holdings, Inc.	Controlled VIE	Controlled VIE	November 2018	59.2%	58.9%
Kures, Inc.	Controlled VIE	Controlled VIE	August 2019	64.5%	64.5%
EntheogeniX Biosciences, Inc.	Wholly Owned Subsidiary	Controlled VIE	November 2019	100.0%	80.0%
DemeRx IB, Inc.	Wholly Owned Subsidiary	Controlled VIE	December 2019	100.0%	59.5%
Recognify Life Sciences, Inc.	Controlled VIE	Controlled VIE	November 2020	51.9%	51.9%
PsyProtix, Inc.	Controlled VIE	Controlled VIE	February 2021	75.0%	75.0%
Psyber, Inc. [1]	-	Controlled VIE	February 2021	—	75.0%
InnarisBio, Inc.	Wholly Owned Subsidiary	Controlled VIE	March 2021	100.0%	82.0%
TryptageniX Inc. [1]	—	Controlled VIE	December 2021	—	65.0%

[1] As discussed in Note 3, the Company deconsolidated Psyber, Inc. and TryptageniX, Inc. in October and December 2023, respectfully.

As of December 31, 2023 and 2022, 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.

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 sheet. 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.

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all VIEs as of December 31, 2023 (in thousands):

	Perception	Kures	EntheogeniX	DemeRx IB	Recognify	PsyProtix	InnarisBio
Assets:							
Current assets:							
Cash	$ 97	$ 257	$ 675	$ 528	$ 4,356	$ 35	$ 326
Accounts receivable	84	—	—	—	—	—	—
Prepaid expenses and other current assets	257	—	124	—	450	—	878
Total current assets	438	257	799	528	4,806	35	1,204
Long term notes receivable	—	—	—	—	—	97	—
Other assets	—	—	—	—	—	—	16
Total assets	$ 438	$ 257	$ 799	$ 528	$ 4,806	$ 132	$ 1,220
Liabilities:							
Current liabilities:							
Accounts payable	$ 31	$ 329	$ 59	$ 51	$ 1,926	$ —	$ —
Accrued liabilities	718	84	247	434	609	26	10
Other current liabilities	12	—	—	2	1	—	1
Total current liabilities	761	413	306	487	2,536	26	11
Total liabilities	$ 761	$ 413	$ 306	$ 487	$ 2,536	$ 26	$ 11

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all consolidated VIEs as of December 31, 2022 (in thousands):

	Perception	Kures	EntheogeniX	DemeRx IB	Recognify	PsyProtix	Psyber	InnarisBio	TryptageniX
Assets:									
Current assets:									
Cash	$ 8,703	$ 220	$ 467	$ 12,251	$ 7,526	$ 1	$ 683	$ 719	$ 513
Accounts receivable	197	—	—	—	—	—	—	—	—
Prepaid expenses and other current assets	466	174	91	21	1,742	66	—	13	2,850
Total current assets	9,366	394	558	12,272	9,268	67	683	732	3,363
Long term notes receivable	—	—	—	1,075	—	109	—	—	—
Other assets	—	—	—	—	—	—	353	—	—
Total assets	$ 9,366	$ 394	$ 558	$ 13,347	$ 9,268	$ 176	$ 1,036	$ 732	$ 3,363
Liabilities:									
Current liabilities:									
Accounts payable	$ 661	$ 25	$ 124	$ 332	$ 381	$ 33	$ 10	$ 3	$ —
Accrued liabilities	1,738	266	121	671	596	46	37	158	154
Other current liabilities	121	2	—	133	2	1	1	1	—
Total current liabilities	2,520	293	245	1,136	979	80	48	162	154
Total liabilities	$ 2,520	$ 293	$ 245	$ 1,136	$ 979	$ 80	$ 48	$ 162	$ 154

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
Issuance of noncontrolling interests	—	—	—	—
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

	Perception	Kures	Recognify	Total
Balance as of December 31, 2021	$ 5,232	$ —	$ 3,819	$ 9,051
Issuance of noncontrolling interests	—	957	—	957
Net income (loss) attributable to noncontrolling interests - preferred	(3,551)	(149)	(975)	(4,675)
Net income (loss) attributable to noncontrolling interests - common	—	(357)	—	(357)
Comprehensive loss attributable to noncontrolling interests	50	—	—	50
Balance as of December 31, 2022	$ 1,731	$ 451	$ 2,844	$ 5,026

Nonconsolidated VIEs

The Company evaluated the nature of its investments in Innoplexus AG ("Innoplexus") and IntelGenx and determined that the investments are VIEs as of the date of the Company's initial investment through the earlier of the date of disposal or December 31, 2023. The Company is not the primary beneficiary 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 that would require consolidation as of December 31, 2023 and 2022.

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. As of December 31, 2023, the Company's maximum exposure for its nonconsolidated VIEs was $6.1 million relating to the carrying values in Other investments held at fair value, $0.1 million relating to the carrying value in Long term notes receivable – related party, and $11.2 relating to Convertible notes receivable - related party. As of December 31, 2022, the Company's maximum exposure for its nonconsolidated VIEs was $6.8 million relating to the carrying values in its Other investments and $7.2 million relating to the carrying value in Long term notes receivable - related party.

5. Equity Method Investments and Other Investments

Equity Method Investments

As of December 31, 2023 and 2022, the Company accounted for the following investments in the investee's common stock under the equity method (in thousands):

		As of December 31, 2023		As of December 31, 2022	
Investee	**Date First Acquired**	**Common Stock Ownership %**	**Carrying Value**	**Common Stock Ownership %**	**Carrying Value**
Innoplexus A.G.	August 2018	35.0%	$ —	35.0%	$ —
COMPASS Pathways plc	December 2018	15.4% (1)	—	22.4%	—
GABA Therapeutics, Inc	November 2020	3.6% (2)	—	7.5% (2)	—
Total			$ —		$ —

(1) The Company accounted for its investment in COMPASS Pathways plc ("COMPASS") under the equity method until August 18, 2023, the closing date of COMPASS's dilutive financing round described below in Other investments held at fair value.

(2) The Company is deemed to have significant influence over GABA Therapeutics, Inc ("GABA") through its total ownership interest in GABA, including the Company's investment in GABA's preferred stock, described below in Other investments. The Company's total ownership interest, considering both preferred and common stock is 54.1%.

Other investments held at fair value

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.The Company's ownership interest in COMPASS as of December 31, 2022, was 22.4%. 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%.

For the year ended December 31, 2022 and the period through August 18, 2023, the Company maintained significant influence through its ownership interest and accounted for its COMPASS investment under the equity method. The carrying value of the Company's COMPASS investment was reduced to zero as of December 31, 2022 due to IPR&D charges with no alternative future use and recognition of its proportionate share of COMPASS net losses. During the year ended December 31, 2022, the Company recognized its proportionate share of COMPASS's net loss of $10.1 million as Losses from investments in equity method investees, net of tax on the consolidated statements of operations.

Following COMPASS's 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. Subsequent to this remeasurement date, the Company's COMPASS investment is accounted for at fair value under ASC 321 and recorded in Other investments held at fair value on the consolidated balance sheets. Any changes in fair value of the Company's COMPASS investment are recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations. Based on quoted market prices, the fair value of the Company's COMPASS investment was $83.7 million as of December 31, 2023. For the year ended December 31, 2023, the Company recorded $81.9 million of Change in fair value of assets and liabilities, net.

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").

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 and warrants to the Company at a price of approximately $12.3 million. Each warrant (the "Initial Warrants") entitles the Company to purchase one share at a price of $0.35 per share for a period of three years from the closing of the initial investment in March 2021. Pursuant to the IntelGenx SPA, the Company has the right to purchase (in cash, or in certain circumstances, the Company's equity) additional units for a period of three years from the closing of the initial investment (the "Additional Unit Warrants"). Each Additional Unit Warrant will be comprised of (i) one share of common stock and (ii) one half of one warrant (the "Additional Warrants"). The price for the Additional Unit Warrants will be (i) until the date which is 12 months following the closing and the purchase does not result in the Company owning more than 74,600,000 common shares of IntelGenx, $0.331 (subject to certain exceptions), and (ii) until the date which is 12 months following the closing and the purchase results in the Company owning more than 74,600,000 common shares of IntelGenx or following the date which is 12 months following the closing regardless of the number of shares held by the Company, the lower of (A) a 20% premium to the volume weighted average price of the common share for the thirty trading days immediately preceding the news release of the additional closing, and (B) $0.50 if purchased in the second year following closing or $0.75, if purchased in the third year following closing. Each Additional Warrant will entitle the Company, for a period of three years from the date of issuance, to purchase one share at the lesser of either (i) a 20% premium to the price of the corresponding additional share, or (ii) the price per share under which shares of IntelGenx are issued under convertible instruments that were outstanding on February 16, 2021, provided that the Company may not exercise Additional Warrants to purchase more than the lesser of (x) 44,000,000 common shares of IntelGenx, and (y) the number of common shares issued by IntelGenx under outstanding convertibles held by other investors as of February 16, 2021.

Following the initial closing, 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 of IntelGenx common shares. The Company has significant influence over IntelGenx through the Company's ownership interest in IntelGenx's equity and its noncontrolling representation on IntelGenx's board of directors.

The Company qualified for and elected to account for its investment in the IntelGenx common stock under the fair value option. The Company believes that the fair value option better reflects the underlying economics of the IntelGenx common stock investment. The Initial Warrants and the Additional Units Warrant are accounted for at fair value under ASC 321 and recorded in Other investments held at fair value on the consolidated balance sheets. The Company applied a calibrated model and determined that the initial aggregate fair value of its $12.3 million investment was equal to the transaction price and recorded the common shares at $3.0 million, the Initial Warrants at $1.2 million and the Additional Unit Warrants at $8.2 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of operations. The Company recognizes subsequent changes in fair value of the common shares, the Initial

Warrants and the Additional Unit Warrants as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. The carrying amount of the investment was reduced to zero as of December 31, 2021. During the years ended December 31, 2023 and 2022, the Company did not recognize a change in fair value in the consolidated statements of operations. The carrying value of the investment remained at zero as of December 31, 2023 and 2022.

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 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 Convertible notes receivable - related party in the consolidated balance sheet, 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 sheet.

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, 2023, the fair value of the 2023 Initial Warrants was $0.7 million. For the year ended December 31, 2023, the Company recognized an immaterial amount in Change in fair value of assets and liabilities, net relating to the 2023 Initial Warrants in its consolidated statements of operations.

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, 2023, the fair value of the 2023 Subsequent Warrants was $0.2 million. For the year ended December 31, 2023, the Company recognized an immaterial amount in Change in fair value of assets and liabilities, net relating to the 2023 Subsequent Warrants in its consolidated statements of operations.

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 sheet. The Call Option is additional value conveyed to the Company relating to its investment in and Strategic Development Agreement with IntelGenx. Accordingly, the Company has also recorded a $5.1 million deferred credit, included in Other liablities in the consolidated balance sheet. As appropriate, the Company will account for the deferred credit as a reduction of research and development expense in its consolidated statements of operation until the credit is exhausted or the Company is no longer receiving goods or services from IntelGenx. As of December 31, 2023, the fair value of the Call Option was $5.2 million. For the year ended December 31, 2023, the Company recognized $0.1 million in Change in fair value of assets and liabilities, net relating to the Call Option in its consolidated statements of operations.

Strategic Development Agreement

Pursuant to the Strategic Development Agreement, the Company engages 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 can 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, 2023 and 2022, research and development expense relating to the Strategic Development Agreement were $0.7 million and $0.5 million, respectively, which was applied as a reduction in research and development expenses in accordance with the Strategic Development Agreement.

Other investments

The Company has accounted for its other investments that do not have a readily determinable fair value under the measurement alternative. As of December 31, 2023 and 2022, 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, 2023	December 31, 2022
GABA Therapeutics, Inc.	$ 1,838	$ 5,387
DemeRx NB, Inc.	—	1,024
Juvenescence Limited	—	344
Total	$ 1,838	$ 6,755

The Company's investments in the preferred stock of Innoplexus, GABA, and DemeRx NB 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, 2023 and 2022 there were no observable changes in price recorded related to the Company's Other Investments.

During the years ended December 31, 2023 and 2022, the Company evaluated all of its other investments to determine if certain events or changes in circumstance during these time periods in 2023 and 2022 had a significant adverse effect on the fair value of any of its investments in nonconsolidated entities. Based on this analysis, the Company did not note any impairment indicators associated with the Company's Other Investments.

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.

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 $2.4 million as of December 31, 2023 and 2022, 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 as of December 31, 2023 and 2022.

The carrying value of the Company's investment in Innoplexus was zero as of December 31, 2023 and December 31, 2022.

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, 2023.

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 323. As of December 31, 2023 and2022, the investment in GABA’s preferred stock was recorded in Other investments in the consolidated balance sheets.

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, 2023, 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 but not the obligation 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. During the year ended December 31, 2023 and 2022 , the Company recognized its proportionate share of GABA’s net loss of $3.6 million and $5.9 million, respectively as Losses from investments in equity method investees, net of tax on the consolidated statements of operations.

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

As of December 31, 2022 the Company's investment in Juvenescence Limited ("Juvenescence") was in common stock, however, it was not able to exercise significant influence over the operating and financial decisions of Juvenescence. 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.

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, 2023
	GABA
Current assets	$ 1,720
Non-current assets	—
Total assets	$ 1,720
Current liabilities	$ 1,546
Non-current liabilities	—
Total liabilities	$ 1,546

	December 31, 2022	
	COMPASS [1]	GABA
Current assets	$ 191,651	$ 3,933
Non-current assets	5,643	—
Total assets	$ 197,294	$ 3,933
Current liabilities	$ 15,596	$ 1,542
Non-current liabilities	418	—
Total liabilities	$ 16,014	$ 1,542

Statements of operations

	Nine Months Ended September 30, 2023	Year Ended December 31, 2023
	COMPASS [1]	GABA
Revenue	$ —	$ —
Loss from continuing operations	$ (98,514)	$ (3,593)
Net loss	$ 85,932	$ (3,593)

	Year Ended December 31, 2022	
	COMPASS [1]	GABA
Revenue	$ —	$ —
Loss from continuing operations	$ (110,403)	$ (5,867)
Net loss	$ (91,505)	$ (5,867)

(1) 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

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.

As of December 31, 2023, and 2022, the DemeRx Note outstanding balance of $0 and $1.1 million, respectively, was recorded in Long term notes receivable - related parties, net on the consolidated balance sheets. For the years ended December 31, 2023, and 2022, the Company did not earn any interest income associated with the DemeRx Note.

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. Although IntelGenx cash flows may be insufficient to meet expenses relating to its operations, considering the underlying collateral and other settlement terms available, the Company deems it probable that it will collect the full value of the IntelGenx Term Loan.

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 is 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 will be subsequently remeasured at each reporting date until settled or converted. The Company will recognize 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.

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 sheet. As of December 31, 2022, the $6.1 million carrying value ($5.5 million of principal and $0.6 million of accrued interest) of the IntelGenx Term Loan was recorded in Long term notes receivable - related parties on the consolidated balance sheet. For the years ended December 31, 2023 and 2022, the Company recognized $0.6 million and $0.4 million of interest income, respectively, associated with the IntelGenx Term Loan. For the year ended December 31, 2023, the Company recorded $0.3 million in Change of fair value of convertible notes receivable - related party for the reduction in fair value of 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 sheet. 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 sheet. 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.

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 year ended December 31, 2023, the Company recognized $0.3 million and an immaterial amount in Change in fair value of assets and liabilities, net relating to the 2023 Initial Notes and 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. As of December 31, 2023, the 2023 Term Loan Note had an outstanding balance of $0.5 million, and the Company recognized an immaterial amount of interest income for the year ended December 31, 2023.

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 As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Cash & 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 parties	$ —	$ —	$ 620	$ 620
Contingent consideration liability	—	—	1,637	1,637
2018 convertible promissory note conversion option	—	—	2,385	2,385
	$ —	$ —	$ 4,643	$ 4,643

	Fair Value Measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Cash & Money market funds	$ 72,334	$ —	$ —	$ 72,334
Investment in securities at fair value:				
Commercial Paper	—	5,958	—	5,958
Corporate Notes/Bonds	—	17,719	—	17,719
U.S. Government Agencies	—	58,819	—	58,819
	$ 72,334	$ 82,496	$ —	$ 154,830
Liabilities:				
Contingent consideration liability - related parties	$ —	$ —	$ 953	$ 953
	$ —	$ —	$ 953	$ 953

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 Company purchases investment grade marketable debt securities which are rated by nationally recognized statistical credit rating organizations in accordance with its investment policy. This policy is designed to minimize the Company's exposure to credit losses and to ensure that the adequate liquidity is maintained at all times to meet anticipated cash flow needs.

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, 2023 and 2022, the Company recognized a $5.5 million and $0.3 million gain related to the change in fair value change 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. For the year ended December 31, 2023, the Company recorded $81.9 million of Change in fair value of assets and liabilities, net.

IntelGenx Technologies Corp.

As described in Note 5 and 6 above, the Company's investment in IntelGenx includes Initial Warrants, Additional Unit Warrants, 2023 Initial Warrants, and 2023 Subsequent Warrants, collectively referred to as the “Warrants”, Common Stock and the IntelGenx Term Loan. The Company determined that the Warrants and the Call Option do not meet the definition of a derivative instrument under ASC 815. The Company has classified the Common Stock 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 are 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.

The fair value of Common Shares is estimated by applying a discount for lack of marketability (DLOM) of 5.0% as of December 31, 2023 and 2022. The Company estimated a DLOM in connection with the valuation of the Common Shares at initial recognition and as of December 31, 2023 and 2022 to reflect the restrictions associated with the Common Shares. As of December 31, 2023 and 2022, the only restriction that remains is the unregistered nature of the Common Shares. The fair value of Common Shares, which is included in Other investments held at fair value in the consolidated balance sheet, was zero as of December 31, 2023 and 2022.

The Initial Warrants, 2023 Initial Warrants, 2023 Subsequent Warrants and Call Option were recorded at fair value utilizing the Black-Scholes option pricing model. 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 Warrants and Call Option, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying common stock. The expected volatility is based on a peer group volatility which is a Level 3 input within the fair value hierarchy.

The fair value of the Initial Warrants, which is included in Other investments held at fair value in the consolidated balance sheet, was zero as of December 31, 2023 and 2022. As of December 31, 2023, the fair value of the 2023 Initial Warrants, 2023 Subsequent Warrants and Call Option was $0.7 million, $0.2 million and $5.2 million, respectively, and recorded in Other investments held at fair value in the consolidated balance sheets.

The significant unobservable inputs that are included in the valuation of the Initial Warrants, 2023 Initial Warrants, 2023 Subsequent Warrants and Call Option as of December 31, 2023 and 2022 are (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 is included in the valuation of the Call Option as of December 31, 2023 is discount rate of 45.9% based on an assessment of IntelGenx credit risk and market yields of companies with similar credit risk.

The fair value of the Additional Units is estimated using a Binomial Lattice in a risk-neutral framework (a special case of the Income Approach). Specifically, the future stock price of the IntelGenx is modeled assuming a Geometric Brownian Motion in a risk-neutral framework. For each modeled future price, the Additional Unit is 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 Additional Units is calculated as the probability-weighted present value over all future modeled payoffs. The fair value of the Additional Units, which is included in Other investments held at fair value in the consolidated balance sheet, was zero as of December 31, 2023 and 2022.

The significant unobservable inputs that are included in the valuation of the Additional Units Warrant as of December 31, 2023 and 2022 are (i) estimated market value of the underlying common stock of $0.13, including discount for lack of marketability and (ii) volatility of 100%.

Convertible notes receivable - related party

The fair value of the 2023 Initial Notes, 2023 Subsequent Notes ,and the IntelGenx Term Loan (collectively "Convertible Notes") at issuance were estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The fair value of the 2023 Initial Notes and the 2023 Subsequent Notes is estimated using a Binomial Lattice in a risk-neutral framework (a special case of the Income Approach). Specifically, the future stock price of the IntelGenx is 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 is 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 is calculated as the probability-weighted present value over all future modeled payoffs. The fair value of the 2023 Initial Notes and 2023 Subsequent Notes was $1.7 million and $.05 million, respectively, and recorded in Convertible notes receivable - related party in the consolidated balance sheets as of December 31, 2023.

The significant unobservable inputs that are included in the valuation of the 2023 Initial Notes and 2023 Subsequent Notes as of December 31, 2023 are (i) discount rate of 45.9% based on an assessment of IntelGenx credit risk and market yields of companies with similar credit risk, (ii) estimated market value of the underlying common stock of $0.13, including discount for lack of marketability and (iii) volatility of 100%.

The fair value of the IntelGenx Term Loan 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 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 on a peer group volatility which is a Level 3 input within the fair value hierarchy. 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 sheet.

The significant unobservable inputs that are included in the valuation of the IntelGenx Term Loan as of December 31, 2023 are (i) discount rate of 45.9% based on an assessment of IntelGenx credit risk and market yields of companies with similar credit risk, (ii) volatility of 100% and (iii) estimated market value of the underlying common stock of $0.13.

Contingent consideration liability - related parties

The contingent consideration liability - related parties in the table above relates to milestone and royalty payments in connection with the acquisition of Perception Neuroscience Holdings, Inc. (“Perception”), and InnarisBio. The fair value of the contingent consideration liability—related parties 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, 2023 and 2022, 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 $0.6 million and $0.6 million as of December 31, 2023 and 2022, respectively.

The fair value of the Perception contingent consideration liability - related parties was calculated using the following significant unobservable inputs:

		December 31, 2023	December 31, 2022
Valuation Technique	Significant Unobservable Inputs	Input Range	Input Range
Discounted cash flow	Milestone contingent consideration:		
	Discount rate	13.5%	13.1%
	Probability of the milestone	28.0%	10.0% - 21.0%
Discounted cash flow with SBM	Royalty contingent consideration:		
	Discount rate for royalties	13.0% - 14.2%	20.0% - 21.1%
	Discount rate for royalties on milestones	13.0% - 14.2%	12.3% - 13.4%
	Probability of success rate	13.4% - 28.0%	10.1% - 21.0%

InnarisBio

The fair value of the contingent milestone and royalty liabilities for InnarisBio was estimated to be $0.0 million and $0.1 million as of December 31, 2023 and 2022, respectively.

Contingent Consideration Liability

The contingent consideration liability in the 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 liability 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, 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 AC 480 and the fair value is adjusted each quarter and reflected in other income and expense in the statement 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, 2023 , 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.

The fair value of the contingent milestone for DemeRx was estimated to be $1.4 million as of December 31, 2023.

The fair value of the DemeRx contingent consideration liability - related parties was calculated using the following significant unobservable inputs:

		December 31, 2023
Valuation Technique	**Significant Unobservable Inputs**	**Input Range**
Discounted cash flow	Milestone contingent consideration:	
	Discount rate	13.9%
	Probability of the milestone	20% - 25%

TryptageniX

The fair value of the contingent liability for TryptageniX was estimated to be $0.2 million and $0.2 million as of December 31, 2023 and 2022, 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 11, in December 2023, a nonrelated party noteholder and the Company entered into a subscription agreement ("2023 Subscription Agreement") which the noteholder exchanged its ATAI Life Sciences AG notes ("Old AG Notes") into the same principal amount of new convertible notes issued by ATAI Life Sciences N.V. ("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 Convertible promissory notes in the consolidated balance sheet. 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 year ended December 31, 2023, the Company recognized a loss of $0.7 million as a result of the change in fair value of the New NV notes.

The Conversion Feature fair value was estimated utilizing the Black-Scholes option pricing model. 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, which is a Level 3 input within the fair value hierarchy.

The significant unobservable input that is included in the valuation of the Conversion Feature as of December 31, 2023 is volatility of 78.6%.

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):

	IntelGenx Convertible Notes Receivable	IntelGenx Investments Held at Fair Value [1]	Contingent Consideration Liability - Related Parties [2]	Contingent Consideration Liability [3]	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, including interest	(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

(1) Includes, Initial Warrants, Additional Unit Awards, 2023 Initial Warrants, 2023 Subsequent Warrants, and Call Option Units

(2) Includes Perception milestone based contingent consideration liability and InnarisBio milestone and royalty based contingent consideration liability

(3) 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

	Contingent Consideration Liability - Related Parties	Warrant Liability
Balance as of December 31, 2021	$ 2,483	$ 336
Change in fair value	(1,480)	(336)
Extinguishment of liability	(50)	—
Balance as of December 31, 2022	$ 953	$ —

8. Prepaid Expenses and Other Current Assets

Prepaid expenses consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Prepaid research and development related expenses	$ 1,822	$ 4,626
Tax receivables	1,752	5,631
Prepaid insurance	1,410	2,034
Other	846	1,745
Total	$ 5,830	$ 14,036

9. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued payroll	$ 4,941	$ 5,260
Accrued accounting, legal, and other professional fees	5,468	3,566
Accrued external research and development expenses	3,031	5,550
Other liabilities	1,101	706
Taxes payable	715	2,224
Total	$ 15,256	$ 17,306

10. Leases

Effective January 1, 2022, the Company adoptions ASU 2016-02, Leases (Topic 842), as amended, using the modified transition approach as of the effective date. The adoption resulted in the recognition of a $0.2 million operating lease right-of-use asset, a $0.1 million current operating lease liability, and a $0.1 million long-term operating lease liability on the Company's consolidated balance sheet related to its existing facility operating lease.

The new standard provided a number of optional practical expedients in transition. The Company elected the “package of practical expedients,” which permitted it to not reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs. As a result, the Company has continued to account for existing leases - i.e. leases for which the commencement date is before January 1, 2022 - in accordance with Topic 840 throughout the entire lease term, including periods after the effective date, with the exception that the Company applied the new balance sheet recognition guidance for operating leases and applied Topic 842 for remeasurements and modifications after the Transition Date. The Company also elected the hindsight expedient in determining the lease term and assessing impairment of right-of-use assets when transitioning to ASC 842. As a result, the Company evaluated the lease term for its existing leases as of the transition date, January 1, 2022.

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. 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, 2023 was 4.2 years. The weighted-average discount rate for the Company’s operating leases as of December 31, 2023 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, 2023	December 31, 2022
Right-of-use assets	Operating lease right-of-use asset, net	$ 1,223	$ 226
Current lease liabilities	Current portion of lease liability	275	180
Non-current lease liabilities	Non-current portion of lease liability	990	44

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, 2023 and 2022 (in thousands):

Lease Cost Components	Statement of Operations Classification	December 31, 2023	December 31, 2022
Operating lease cost	Operating expenses: General and administrative	$ 663	$ 266
Short-term lease cost	Operating expenses: General and administrative	338	434
Total lease cost		$ 1,001	$ 700

Future minimum commitments under all non-cancelable operating leases are as follows (in thousands):

Year Ended	
2024	$ 415
2025	370
2026	370
2027	370
2028	123
Total lease payments	1,648
Less: Imputed interest	(383)
Present value of lease liabilities	$ 1,265

Supplemental cash flow information related to the Company's operating leases for the year ended December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 440	$ 267
Right-of-use assets obtained in exchange for new operating lease liabilities	1,377	487

11. Debt

Convertible Promissory Notes

2018 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 "2018 Convertible Notes"). The 2018 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 2018 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 2018 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 2018 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 2018 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.

Conversion of 2018 Convertible Promissory Notes - Related Parties

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 2021, several noteholders elected to convert their convertible promissory notes into shares of ATAI Life Sciences N.V. These investors paid €17.00 per share for an aggregate amount of €5.8 million or $6.9. million in order to convert their convertible promissory notes into ATAI Life Sciences AG common shares, which was in accordance with the original terms of the 2018 Convertible Note Agreements.

In May 2022 and July 2022, certain noteholders elected to convert some of their convertible promissory notes into shares of ATAI Life Sciences N.V. The investors paid €17.00 per share for the aggregate amount of €4.6 million or $4.6 million in order to convert their convertible promissory notes into ATAI Life Sciences AG common shares, which was in accordance with the original terms of the 2018 Convertible Note Agreements.

In 2023, certain noteholders elected to convert some of their convertible promissory notes into shares of ATAI Life Sciences N.V for an immaterial amount.

The Company accounted for the conversion of the 2018 Convertible Notes as a conversion such that carrying values of these notes were derecognized with an offset to common stock at par of ATAI Life Sciences AG and the excess of the carrying values of these notes over the common stock at par of ATAI Life Sciences AG was recorded as additional paid-in capital. Concurrently, with the conversion of the 2018 Convertible Notes into ATAI Life Sciences AG shares, the shares of ATAI Life Sciences AG that were issued to the noteholders were exchanged for shares of ATAI Life Sciences N.V. through a transfer and sale arrangement. As ATAI Life Sciences AG continued to remain a wholly owned subsidiary of ATAI Life Sciences N.V., the transaction was accounted for as an equity transaction that resulted in no gain or loss recognition.

The carrying amounts of the Company's remaining 2018 Convertible Notes do not approximate fair value because the fair value is driven by the underlying value of the Company's common stock into which the notes are to be converted. As of December 31, 2023, the carrying amount and fair value amount of the notes was $0.2 million and $1.5 million, respectively. As of December 31, 2022, the carrying amount and fair value amount of the 2018 Convertible Notes was $0.4 million and $13.1 million, respectively.

2018 Convertible Promissory Notes

Exchange of 2020 Convertible Promissory Notes

In November 2023, a nonrelated party noteholder of the October 2020 notes and ATAI Life Sciences AG executed an exchange agreement ("2023 Exchange Agreement") where the noteholder agreed to exchange its 2020 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 N.V. ("New NV Notes"). The New NV Note 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 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. 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, the Company and the same noteholder entered into a subscription agreement ("2023 Subscription Agreement") and exchanged its Old AG Notes into New NV Notes. The Company determined that the note exchange was a modification of the debt. The 2023 Exchange Agreement and 2023 Subscription Agreement resulted in the new NV Notes conversion option no longer meeting the

equity classification criteria. Accordingly, at the time of the 2023 Exchange Agreement 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 sheet. 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 year ended December 31, 2023, the Company recognized a loss of $0.7 million as a result of the change in fair value of the New NV notes.

As of the year ended December 31, 2023, the carrying value of the Convertible promissory note was $2.7 million, which includes the principal amount and the fair value of the conversion option.

Term Loan

Hercules Loan and Security Agreement

In August 2022, the Company and certain subsidiaries, as guarantors, and Hercules Capital, Inc. 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 (the "2022 Term Loan Facility").

On May 26, 2023, ATAI Life Sciences N.V. (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 to Loan and Security Agreement (the "Amendment"), with the several banks and other financial institutions or entities from time to time parties to the Hercules Loan Agreement (collectively, the "Lenders") and Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and for the Lenders (the "Agent") which amends that certain Loan and Security Agreement, dated August 9, 2022 (as amended by that certain First Amendment to Loan and Security Agreement dated as of March 13, 2023, the "Existing Loan Agreement," and as amended by the Amendment, the "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 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 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.

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 achieves certain performance milestones, 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, 2024, and satisfies certain other specified conditions. 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 4.55% and (ii) 8.55%. 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, for a period of thirty (30) months following the Closing Date, which period may be extended to (i) thirty-six months if certain additional performance milestones have been achieved; and (ii) forty-two months if certain additional performance milestones have been 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 Hercules 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 Loan Agreement requires that beginning on the later of (i) July 1, 2023 and (ii) the date on which the aggregate outstanding amount borrowed under the 2022 Term Loan Facility is equal to or greater than $40.0 million, the Company shall maintain Qualified Cash in an amount no less than the sum of (1) 33% 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, 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 ATAI NV 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, 2023, 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 original principal amount of the term loans so repaid or prepaid under the 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.

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, 2023 and 2022, respectively, interest expense included $0.4 million and $0.1 million of amortized deferred financing costs related to the 2022 Term Loan Facility.

Outstanding debt obligations are as follows (in thousands):

	December 31, 2023	December 31, 2022
Principal amount	$ 15,000	$ 15,000
End of the term charge	1,042	1,042
Less: unamortized issuance discount	(204)	(274)
Less: unamortized issuance costs	(84)	(113)
Less: unamortized end of term charge	(707)	(952)
Net carrying amount	15,047	14,702
Less: current maturities	—	—
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 15,047	$ 14,702

The fair value of the outstanding Hercules debt obligations was $16.2 million and $14.9 million as of December 31, 2023 and 2022, respectively. The fair value of the Hercules debt obligations represent Level 3 measurements within the fair value hierarchy.

12. Common Stock

In November and December 2020, the Company issued and sold 14,933,344 shares of common stock of €0.10 par value to new and existing investors, including related parties, at a price of €4.69 or $5.56 per share, for proceeds of $77.2 million, net of issuance costs of $5.2 million which includes advisory fees paid to Small & Mid Cap Investmentbank AG ("SMC"). SMC paid a portion of the advisory fees received from the Company to Apeiron (see Note 17).

In November 2020, in connection with the Company's issuance and sale of its common stock, all of the outstanding principal and accrued interest under the 2020 Convertible Notes, totaling $32.2 million, was automatically converted into 8,773,056 shares of common stock pursuant to their original terms. Once the notes were converted, the converted shares were recorded at fair value of $5.56 per share price equal to the price per share of common stock issued in November 2020.

In January 2021, pursuant to an additional closing from the common stock issuance in November and December 2020, the Company issued and sold 2,133,328 shares of common stock to Apeiron at the same issuance price, for cash proceeds of $12.2 million. In March 2021, the

Company issued and sold 13,419,360 shares of common stock to new and existing investors, including related parties, at a price of €9.69 or $11.71 per share, for cash proceeds of $152.2 million, net of issuance costs of $4.9 million.

On June 22, 2021, atai closed the IPO of its common stock on Nasdaq. As part of the IPO, the Company issued and sold 17,250,000 shares of its common stock, which included 2,250,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $15.00 per share. The Company received net proceeds of $231.6 million from the IPO, after deducting underwriters' discounts and commissions of $18.1 million and offering costs of $9.0 million.

All common shareholders have identical rights. Each share of common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote.

All holders of common stock are entitled to receive dividends, as may be declared by the Company's board of directors. Upon liquidation, common stockholders will receive distribution on a pro rata basis. As of December 31, 2023 and 2022, no cash dividends have been declared or paid.

13. Stock-Based Compensation

atai Equity Incentive Plans

Stock Option activity under 2020 Incentive Plan and 2021 Incentive Plan

The stock options outstanding noted below consist primarily of both service and performance-based options to purchase common stock. These stock options have a five-year or 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.

Atai Life Sciences 2020 Equity Incentive Plan

Effective August 21, 2020, the Company adopted an equity-based compensation plan, the 2020 Employee, Director and Consultant Equity Incentive Plan (as amended from time to time, "2020 Incentive Plan"). The 2020 Incentive Plan is administered by the Company's 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 and to provide additional incentive for them to promote the success of the Company. The 2020 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 employees and consultants of the Company.

The Company has reserved up to 22,658,192 shares of common stock, excluding any shares issued under its Hurdle Share Option Program ("HSOP") described below, for issuance to executive officers, directors, other employees and consultants of the Company pursuant to the 2020 Incentive Plan. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. As of December 31, 2023, there were no shares available for future grants under the 2020 Incentive Plan and any shares subject to outstanding options originally granted under the 2020 Equity 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 atai Life Sciences 2021 Incentive Award Plan discussed 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 55,035,590 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 8,033,850 and 8,296,796 shares of common stock effective January 1, 2022 and 2023, respectfully. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. As of December 31, 2023, 33,866,036 shares were available for future grants under the 2021 Incentive Plan.

Stock Options

The stock options outstanding noted below consist primarily of both service and performance-based options to purchase Common Stock. 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, 2022 to December 31, 2023:

	Number of Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	34,880,603		$ 5.98	5.71	$ 10,647
Granted	10,425,028	(1)	1.29	—	—
Exercised	(74,562)		2.44	—	—
Cancelled or forfeited	(6,164,615)		5.77	—	—
Outstanding as of December 31, 2023	39,066,454	(2)	$ 4.62	5.56	$ 6,294
Options exercisable as of December 31, 2023	22,314,503		$ 5.40	3.67	$ 4,410

(1) Includes (a) 9,835,328 stock options that will vest over a four-year service period (b) 452,700 stock options that will vest over a one-year service period and (c) 137,000 stock options that will vest over a two-year service period.

(2) Includes 16,751,951 outstanding unvested stock options; (a) 15,138,297 that will continue to vest over a one to four-year service period, (b) 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, (c) 137,000 stock options that will continue to vest over a two-year service period, (d) 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 price of the Company's publicly traded shares, and (e) 384,000 stock options that will vest on the one-year anniversary of the date of grant.

The weighted-average grant-date fair value of options granted during the year months ended December 31, 2023 and 2022 was $1.02 and 3.17.

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, 2023 and 2022, the assumptions used in the Black-Scholes option pricing model were as follows:

	Years Ended December 31,	
	2023	2022
Weighted average expected term in years	6.23	5.89
Weighted average expected stock price volatility	85.7%	71.7%
Risk-free interest rate	3.50% - 4.18%	1.46% - 4.31%
Expected dividend yield	0%	0%

For the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense of $27.9 million and $37.1 million, respectively.

As of December 31, 2023, total unrecognized compensation cost related to the unvested stock-based awards was $34.5 million, which is expected to be recognized over a weighted average period of 1.92 years.

Restricted stock units

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, 2022 to December 31, 2023:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested at January 1, 2023	—	$ —
Granted	3,251,815	1.18
Vested	—	—
Forfeited	306,880	1.18
Unvested at December 31, 2023	2,944,935	$ 1.18

For the years ended December 31, 2023, the Company recorded stock-based compensation expense of $1.4 million.

The total fair value of restricted stock units vested during the year ended December 31, 2023 was $0. As of December 31, 2023, total unrecognized compensation cost related to the unvested stock-based awards was $2.0 million, which is expected to be recognized over a weighted average period of 1.19 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 (so-called Hurdle Share Options Program or "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, 2023, 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, 2023, 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), which occurred on April 23, 2021 currently with the corporate reorganization discussed in Note 1.

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. If a Change in Control (as defined in the Partnership agreement) or in the event the holder's service with the Partnership is terminated due to his death or disability

by June 30, 2021 or December 31, 2021, an additional 25% or 12.5%, respectively, HSOP Options will accelerate and vest upon the occurrence of the transaction. 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 from December 31, 2022 to December 31, 2023:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	6,921,829	$ 6.64	13.01	$ —
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled or forfeited	—	—	—	—
Outstanding as of December 31, 2023	6,921,829	$ 6.64	12.01	$ —
Options exercisable as of December 31, 2023	6,754,232	$ 6.64	12.01	$ —

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, 2023 and 2022. For the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense of $3.1 million and $4.5 million, respectively.

As of December 31, 2023, total unrecognized compensation cost related to the unvested stock-based awards was $0.1 million which is expected to be recognized over a weighted average period of 0.1 years.

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, 2023 and 2022, the Company recorded stock-based compensation expense of $0.5 million and $0.7 million, respectively, in relation to subsidiary EIPs. As of December 31, 2023, there was $0.2 million 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 0.6 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, 2023, which includes expense related to stock options and restricted stock awards (in thousands):

	Year Ended December 31, 2023			
	atai IAP	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 share based compensation expense	$ 29,465	$ 3,052	$ 465	$ 32,982

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2022, which includes expense related to stock options and restricted stock awards (in thousands):

	Year Ended December 31, 2022			
	atai IAP	atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ 15,797	$ —	$ 527	$ 16,324
General and administrative	21,333	4,551	167	26,051
Total share based compensation expense	$ 37,130	$ 4,551	$ 694	$ 42,375

14. Income Taxes

The component of German and overseas income (loss) from continuing operations before income taxes is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Germany	$ 19,916	$ (55,845)
International	(59,201)	(79,337)
Total loss before income taxes and loss from equity method investments	$ (39,286)	$ (135,182)

The tax provision (benefits) for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2023	2022
Current income tax provision:		
Germany	$ —	$ —
International	1,016	1,155
Total current income tax provision:	$ 1,016	$ 1,155
Deferred income tax provision:		
Germany	$ —	$ —
International	—	5,074
Total deferred income tax provision:	—	5,074
Total income tax provision:	$ 1,016	$ 6,229

The international current tax provision for December 31, 2023 and 2022 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):

	Years Ended December 31,	
	2023	2022
Loss before income taxes:		
Germany	$ 19,916	$ (55,845)
International	(59,201)	(79,337)
Total loss before income taxes:	(39,286)	(135,182)
German statutory rate	30.18%	30.18%
Expected income tax benefit	(11,856)	(40,791)
US state income taxes, net of US federal tax benefit	$ (3,662)	$ (6,509)
International tax rate differential	5,188	7,276
Effect of Australian R&D tax credit incentives	582	(338)
Effect of taxes not provided on outside basis differences in investments regarding: fair value adjustments	—	(109)
Effect of consolidation and deconsolidation of subsidiaries	3,250	(1,394)
Effect of share-based compensation expense	975	216
Effect of non-deductible US compensation expense under IRC Section 162(m)	1,368	411
Expenses not deductible for tax purposes	600	(324)
Effect of statutory to US GAAP accounting adjustments	—	98
Return to Provision and deferred tax adjustments	10,188	758
Uncertain Tax Positions	96	—
Change in German and international valuation allowance	(5,713)	46,935
Total income tax expense	$ 1,016	$ 6,229
Effective income tax rate:	-2.59%	-4.61%

The Company is headquartered in Berlin, Germany and has subsidiaries in the United States, Australia, the United Kingdom, and Singapore 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, 2023 and 2022 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, 2023 and 2022 was 21.00%. The weighted-average Australia corporate income tax rate for the year ended December 31, 2023 and 2022 was 25.00%. In 2023 it was noted that atai Therapeutics 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, 2023 and 2022 was 25.00% and 19.00%, respectively. The Singapore corporate income tax rate for the year ended December 31, 2023 was 17.00%.

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):

	As of December 31,	
	2023	2022
Deferred tax assets:		
German tax loss carryforward	$ 49,014	$ 45,560
International tax loss carryforward	16,270	10,585
Share compensation	35,062	31,078
Capitalized research and experimentation expenses	19,312	11,975
Operating lease right-of-use liability	13	-
Other deductible timing differences	1,127	1,864
Total deferred tax assets, gross	120,798	101,062
Valuation allowance	(89,968)	(95,678)
Total deferred tax assets, net	$ 30,830	$ 5,384
Deferred tax liabilities:		
Fixed and intangible assets	$ (930)	$ (908)
Unrealized foreign exchange	(4,904)	(4,472)
Outside basis differences in equity and other investments	(2)	(4)
Investments	(24,982)	—
Operating lease right-of-use asset	(12)	—
Total deferred tax liabilities	(30,830)	(5,384)
Total deferred tax asset	$ —	$ —

The valuation allowance provided against net deferred tax assets as of December 31, 2023 and 2022 was $90.0 million and $95.7 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 2022, 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 2023 and 2022. 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 2023 were performed outside of the United States and are amortizable over a 15 year period.

In assessing the realizability of deferred tax assets, management 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. Management considers the Company’s 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, our income tax provision would increase or decrease in the period in which the assessment is changed.

We note that 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, 2023 and 2022 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,	
	2023	2022
Germany tax losses	$ 162,436	$ 150,991
International tax losses	56,691	41,908
Total	$ 219,127	$ 192,899

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. is currently under routine audit by the Internal Revenue Service. 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, 2023 and 2022, the Company the Company notes the following unrecognized tax benefits.

	Year Ended December 31,	
	2023	2022
Balance at beginning of period	$ —	$ —
Increases—prior year tax positions	—	—
Decreases—prior year tax positions	—	—
Increases—current year tax positions	369	—
Balance at end of period	$ 369	$ —

The balances of unrecognized tax benefits as of December 31, 2023 was $0.4 million, which represent the amounts that, if recognized, impact the effective income tax rate in future periods.

15. 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):

	Years Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (43,895)	$ (157,417)
Net loss attributable to noncontrolling interests	(3,671)	(5,032)
Net loss attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (40,224)	$ (152,385)
Denominator:		
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. Stockholders - basic and diluted	158,833,785	155,719,585
Net loss per share attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (0.25)	$ (0.98)

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,	
	2023	2022
Options to purchase common stock	39,066,454	34,880,604
HSOP options to purchase common stock	6,921,829	6,921,829
2018 convertible promissory notes - related parties	2,367,200	6,201,824
2018 convertible promissory notes	3,818,704	—
Unvested restricted stock units	2,944,935	—
	55,119,122	48,004,257

As of December 31, 2023 and 2022, the remaining 2018 convertible promissory notes - related parties would be issuable upon the exercise of conversion rights of convertible note holders for 147,950 and 387,614 shares of common stock of ATAI Life Sciences AG, respectfully. Upon conversion, it is expected that the remaining 2018 convertible promissory notes - related parties would be exchanged on a one-for-sixteen basis for shares of ATAI Life Sciences N.V. which is reflected in the table above. See the Debt note to the Consolidated Financial Statements.

As of December 31, 2023, the remaining 2018 convertible promissory notes would be issuable upon the exercise of conversion rights of convertible note holders for 3,818,704 shares of common stock of ATAI Life Sciences N.V. See the Debt note to the Consolidated Financial Statements.

16. 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, 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 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 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. The Company currently believes that the outcome of these legal proceedings, either individually or in the aggregate, will not have a material effect on its consolidated financial position, results of operations or cash flows.

17. License Agreements

Otsuka License and Collaboration Agreement

On March 11, 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. Under the terms of the Otsuka Agreement, Otsuka received an exclusive right to develop and commercialize products containing PCN-101 in Japan at its own cost and expense. Perception retained all rights to PCN-101 outside of Japan.

Otsuka owed Perception an upfront, non-refundable payment of $20.0 million as of the execution of the Otsuka Agreement. 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.

The Otsuka Agreement will expire upon the fulfillment of Otsuka's royalty obligations on a product-by-product basis. Otsuka shall have the right to terminate this agreement in its entirety for convenience at any time (a) on ninety (90) days' prior written notice to Perception if such notice is given before the first regulatory approval of the first licensed product in the Otsuka territory, or (b) on one hundred and eighty (180) days' prior written notice to Perception if such notice is given on or after the first regulatory approval of the first licensed product in the Otsuka territory. The Otsuka Agreement may be terminated in its entirety at any time during the term upon written notice by either party if the other party is in material breach of its obligations and has not cured such breach within thirty (30) days in the case of a payment breach, or within ninety (90) days in the case of all other breaches.

The Company first assessed the Otsuka Agreement under ASC 808 to determine whether the Otsuka Agreement or units of accounts within the Otsuka Agreement represent a collaborative arrangement based on the risks and rewards and activities of the parties.

The Company concluded that Otsuka is a customer in the context of the Otsuka Agreement and the units of account are within the scope of ASC 606. The Company determined that the combined promise of the exclusive license to PCN-101 and non-exclusive license to conduct clinical trials in Asia are a single performance obligation. The Company determined that the option rights for CMC study data, additional research services and development supply do not represent material rights to Otsuka as these options were issued at standalone selling prices. As such, they are not performance obligations at the outset of the arrangement.

Based on this assessment, the Company concluded three performance obligations exists at the outset of the Otsuka Agreement: (i) the exclusive license to PCN-101 and exclusive license to conduct clinical trials in Japan, (ii) Global Requested Ongoing Clinical Studies and (iii) Global Ongoing Clinical Studies. The Company determined that the upfront payment of $20.0 million constitutes the transaction price at the outset of the Otsuka Agreement. Future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved. The achievement of the future potential milestones is not within the Company's control and is subject to certain research and development success or regulatory approvals and therefore carry significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. As all performance obligations will have been satisfied in advance of the achievement of the milestone events, if the risk of significant revenue reversal is resolved, any future milestone revenue from the arrangement will be added to the transaction price (and thereby recognized as revenue) in the period the risk is resolved.

For the years ended December 31, 2023 and 2022, there were no additional milestones achieved under the Otsuka Agreement. The Company recognized revenues of $0.3 million and $0.2 million related to certain research and development services during the years ended December 31, 2023 and 2022, 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, 2023 and 2022, respectively, the Company made no 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 year ended December 31, 2021, the Company made no material payments pursuant to the Allergan License Agreement.

During the years ended December 31, 2023 and 2022, respectively, the Company made no 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.

During the years ended December 31, 2023 and 2022, Kures made no 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 year ended December 31, 2023 and 2022, the Company recorded $2.0 million and $2.8 million, respectively as research and development expense. During the years ended December 31, 2023 and 2022, Invyxis made no other service fee payments to Dalriada.

18. 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 19.7% and 19.7% of the outstanding common stock in the Company as of December 31, 2023 and 2022, respectively. Galaxy is a NYC-based multi-strategy investment firm that owns 6.5% and 6.5% of the outstanding common stock in the Company as of December 31, 2023 and 2022, respectively.

Directed Share Program

In connection with atai's initial public offering, the underwriters reserved 27% of the common shares for sale at the initial offering price to the Company's managing directors, supervisory directors and certain other parties. Apeiron participated in the program and purchased $10.5 million of common stock

Consulting Agreement with Mr. Angermayer

In January 2021, the Company entered into a consulting agreement, (the "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, this agreement was terminated, as further described in the Subsequent Events footnote below.

As a result of the Consulting Agreement, year ended December 31, 2023 and 2022, the Company recorded $0.7 million and $0.7 million, respectively, of stock-based compensation included in general and administrative expense in its consolidated statements of operations.

For the year ended December 31, 2023 and 2022, the Company recorded $0.6 million 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 supervisory board.

19. 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 recognized $0.5 million and $0.5 million of related compensation expense for the years ended December 31, 2023 and 2022.

20. Corporate 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 was incurred primarily during the year ended December 31, 2023, resulting 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 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 statement of operations.

As of December 31, 2023, all restructuring liabilities had been paid in full and the Company had $0.0 of restructuring liabilities included in accrued expenses on the Company's consolidated balance sheets.

21. Subsequent Events

Following the events took place subsequent to the year ended December 31, 2023:

The Company entered into a subscription and shareholders' agreement with Beckley Psytech Limited ("Beckley Psytech") pursuant to which the Company acquired a 35.5% interest in the voting securities of BPL. This is based on a $50m total investment, with a $40m direct investment into Beckley Psytech and an additional $10m in secondary share purchases from existing shareholders. Upon closing, atai received 1:1 warrant coverage at a 30% premium on the primary issuances. atai will also have the right to appoint and hold 3 of the 9 seats in Beckley Psytech's Board of Directors, and will hold a time-limited right of first refusal on a future sale of the company, asset sales or other transfer of commercial rights, as well as an indefinite right of first negotiation for BPL-003 and ELE-101. As of December 31, 2023, the Company had deposited $25 million with Beckley Psytech's legal counsel, which was paid to Beckley Psytech at closing.

The Company identified redundancies among certain positions, which resulted in a reduction in force of approximately 10% of the Company's global workforce.

The Company and IntelGenx entered into a third amended and restated loan agreement, pursuant to which, among other things, the Company made a $1.0 million additional term loan following the execution and has agreed to make an additional $1.0 million term loan to be disbursed upon the achievement of a pre-defined milestone.

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 Consultancy Agreement (as defined above) between ATAI AG and Mr. Angermayer dated January 16, 2021 (the "Original Consultancy Agreement") and enter into a new consultancy agreement between the Company and Mr. Angermayer to, among other things, extend the term of the Original 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.

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, 2023. 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, 2023 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, 2023, 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, 2023.

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, 2023, 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, 2023 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2023 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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.life. 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 2023.

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
Florian Brand	37	Co-Founder and Chief Executive Officer	Same
Srinivas Rao, Ph.D.	55	Co-Founder and Chief Scientific Officer	Same
Anne Johnson	55	Chief Financial Officer	Same
Sahil Kirpekar	39	Chief Business Officer	Same
Christian Angermayer	45	Founder and Chairman	Founder of Apeiron Investment Group, an investment company
Michael Auerbach	48	Supervisory Director	Founder of Subversive Capital, a private equity firm
Jason Camm	35	Supervisory Director	Managing Director and Chief Medical Officer at Thiel Capital, an investment company
Sabrina Martucci Johnson	57	Supervisory Director	Founder and Chief Executive Officer of Daré Bioscience, Inc., a biopharmaceutical company
Amir Kalali, M.D.	58	Supervisory Director	Professor of Psychiatry at the University of California San Diego
Andrea Heslin Smiley	56	Supervisory Director	President and Chief Executive Officer of VMS BioMarketing, a biomarketing company

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2024 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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#	Service Agreement, dated June 5, 2019, between the Registrant and Florian Brand, as amended by agreement dated June 10, 2021	S-1/A	333- 255383	10.1	6/11/2021	
10.2#	Amended and Restated Employment Agreement, dated June 9, 2021, between ATAI Life Sciences US, Inc. and Srinivas Rao	S-1/A	333- 255383	10.3	6/11/2021	
10.3#	Amended and Restated Employment Agreement, dated June 9, 2021, between Rolando Gutiérrez Esteinou and ATAI Life Sciences US, Inc.	S-1/A	333- 255383	10.25	6/11/2021	
10.4#	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	
10.5#	Employment Agreement, dated November 8, 2022, by and between Stephen Bardin and atai Life Sciences AG	10-Q	001-40493	10.2	11/10/2022	
10.6#	Atai Life Sciences N.V. 2021 Incentive Award Plan	S-1/A	333- 255383	10.5	6/11/2021	
10.7#	Form of Option Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.17	6/11/2021	

10.8#	Form of Restricted Stock Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.18	6/11/2021
10.9#	Form of Restricted Stock Unit Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.19	6/11/2021
10.10#	2020 Employee, Director, and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.20	6/11/2021
10.11#	Form of Stock Option Agreement under 2020 Employee, Director and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.21	6/11/2021
10.12#	Remuneration Policy for the Board of Supervisory Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.23	6/11/2021
10.13#	Remuneration policy for the Board of Managing Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.24	6/11/2021
10.14†	Stock Purchase Agreement, dated as of November 5, 2018, by and between ATAI US 2, Inc. and Jonathan Sporn	S-1	333-255383	10.7	4/20/2021
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†	Exclusive License 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	10.10	4/20/2021
10.18†	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
10.19†	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
10.20†	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
10.21†	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

10.22#†	Consultancy Agreement, dated as of January 16, 2021, between ATAI Life Sciences AG and Christian Angermayer	S-1	333-255383	10.15	4/20/2021
10.23†	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
10.24	Partnership Agreement of ATAI Life Sciences HSOP GbR, dated August 21, 2020	S-1/A	333-255383	10.22	6/11/2021
10.25	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
10.26†	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
10.27	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, 2022	10-K	001-40493	10.27	3/24/2023
10.28†	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
10.29†	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
10.30†	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
10.31#	Amended Executive Employment Agreement dated August 25, 2023 between Stephen Bardin and ATAI Life Sciences US, Inc.	8-K	001-40493	10.1	8/31/2023
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†	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	
10.35	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	
10.36†	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	
10.37†	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	
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					*
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 28, 2024

By: /s/ Florian Brand
Florian Brand
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/ Florian Brand Florian Brand	Chief Executive Officer and Managing Director (Principal Executive Officer)	March 28, 2024
/s/ Anne Johnson Anne Johnson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28 2024
/s/ Christian Angermayer Christian Angermayer	Chairman of the Supervisory Board	March 28, 2024
/s/ Michael Auerbach Michael Auerbach	Supervisory Director	March 28, 2024
/s/ Jason Camm Jason Camm	Supervisory Director	March 28, 2024
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Supervisory Director	March 28, 2024
/s/ Amir Kalali Amir Kalali	Supervisory Director	March 28, 2024
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Supervisory Director	March 28, 2024

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;
- 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; and

- the Company may not make calls on shareholders in excess of the aggregate nominal value of the shares a shareholder has subscribed for.

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 whereas 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. The 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 and enjoyment (*vruchtgebruik*) on 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 may 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.

General meetings of shareholders must be convened by a notice published in a Dutch daily newspaper with national distribution or by a notice in an electronic communication system, which each 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. 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 Dutch Corporate Governance Code (DCGC) and our articles of association, shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting of shareholders. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting of shareholders and shall not apply: (a) in respect of a matter for which a response period has been previously invoked or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting of shareholders be convened, as described above.

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

- ther 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 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.

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.

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, 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

We may only make distributions to our shareholders if our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-up and called-up share capital plus any reserves required by Dutch law or by our articles of association. Under our articles of association, the management board may decide that all or part of the profits shown in our adopted annual accounts are carried to reserves. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders at the proposal of our board for distribution, subject to restrictions of Dutch law and approval by our supervisory board.

We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. 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, anti-money laundering regulations and similar rules.

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 debts, those assets shall be distributed to the holders of common 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 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 they do 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 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 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 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, 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. The managing directors may divide their tasks among themselves in or pursuant to the internal rules applicable to the management board. 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 resolutions of the 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 stockholders. 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 stockholders.

Director Terms

The Netherlands. The DCGC provides the following best practice recommendations on the terms for tenure of 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 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 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 stockholders. A director

elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Director Vacancies

The Netherlands. Our supervisory board can temporarily fill vacancies in its midst caused by temporary absence or incapacity of supervisory directors without requiring a shareholder vote. If all of our supervisory directors are absent or incapacitated, our management shall be attributed to the person who most recently ceased to hold office as the chairperson of our supervisory board, provided that if such former chairperson is unwilling or unable to accept that position, our management shall be attributed to the person who most recently ceased to hold office as our Chief Executive Officer. If such former Chief Executive Officer is also unwilling or unable to accept that position, our management shall be attributed to one or more persons whom the general meeting. The person(s) charged with our management in this manner may designate one or more persons to be charged with our management instead of, or together with, such person(s).

Under Dutch law, managing directors and supervisory directors of a company like ours 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 stockholders.

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 stockholder 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.

Stockholders 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 stockholders of record entitled to notice or to vote at a meeting of stockholders 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 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 board to

convene a general meeting of shareholders and or board has not taken the necessary steps so that the general meeting of shareholders could be held within six weeks after the request.

Also, the agenda for a general meeting shall 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 and our articles of association, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

Delaware. Delaware law does not specifically grant stockholders 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 stockholder 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 stockholders 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 stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder'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, directors and officers can still be subject to liability under U.S. securities laws.

Delaware. Under the DGCL, a stockholder 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 stockholders 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 stockholder 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 stockholder 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. Our management board, subject to approval by our supervisory board, is authorized, for a period of 18 months after we converted into the legal form of an N.V. to cause the repurchase of common shares by us of up to 20% of our issued share capital, for a price per share not exceeding 110% of the average market price of our common shares on Nasdaq (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by us). These shares may be used to deliver shares underlying awards granted pursuant to our equity-based compensation plans.

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 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 or our former CEO, as applicable, to manage our affairs if all of our managing directors and supervisory directors are removed from office and to appoint others to be charged with the management and supervision of our affairs, until new managing directors and 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 one year.

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 stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder 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 stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or

- after the person becomes an interested stockholder, 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 stockholder.

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 stockholder 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, the general meeting shall at all times be entitled to dismiss a managing director or supervisory director. The general meeting may only adopt a resolution to suspend or dismiss a managing director or supervisory 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 proposal was made by the supervisory board, in which latter case a simple majority is sufficient. The DCGC recommends that the general meeting can pass a resolution to dismiss a 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, stockholders 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. Our management board, with the approval of our supervisory board, is authorized, for a period of five years after we converted into the legal form of an N.V., to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time. 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. Our management board, with the approval of our supervisory board, is authorized, for a period not exceeding five years after we converted into the legal form of an N.V. to limit or exclude preemptive rights in relation to an issuance of shares or a grant of rights to subscribe for shares that the management board is authorized to resolve upon (see "Issuance of Shares" above).

Delaware. Under the DGCL, stockholders 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. Dutch law provides that dividends (if it concerns a distribution of profits) may be distributed after adoption of the annual accounts by the general meeting from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed, whether as a distribution of profits or of freely distributable reserves, only to the extent the shareholders' equity exceeds the amount of the paid-in and called-up issued share capital and the reserves that must be maintained under the law or the articles of association. Interim dividends may be declared as provided in the articles of association and may be distributed to the extent that the shareholders' equity exceeds the amount of the paid-in and called-up issued share capital plus any reserves as described above as apparent from our interim financial statements prepared under Dutch law.

Under our articles of association, our management board, with the approval of our supervisory board, may decide that all or part of the profits are carried to reserves. After reservation of any profit, the remaining profit 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 stockholders 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, stockholders 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 stockholders 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 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. 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 stockholders 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 stockholder vote due to the provisions of U.S. federal securities and tax law.

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
DemeRx IB, Inc.*	Delaware
EmpathBio, Inc.	Delaware
EntheogeniX Biosciences, Inc.*	Delaware
GABA Therapeutics, Inc.	Delaware
InnarisBio, Inc.*	Delaware
IntroSpect Digital Therapeutics, Inc.*	Delaware
Invyxis, Inc.*	Delaware
Kures Inc.	Delaware
Perception Neuroscience Holdings, Inc.	Delaware
PsyProtix, Inc.	Delaware
Recognify Life Sciences, Inc.	Delaware
Revixia Life Sciences, Inc.*	Delaware

*Merged into Atai Therapeutics, Inc. as of December 30, 2023

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 28, 2024, 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, 2023.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey March 28, 2024

Exhibit 31.1

CERTIFICATION

I, Florian Brand, 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 28, 2024

By: /s/ Florian Brand

Florian Brand
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 28, 2024

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, 2023 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 28, 2024

By: /s/ Florian Brand
Florian Brand
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, 2023 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 28, 2024

By: /s/ Anne Johnson
Anne Johnson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 97.1

ATAI LIFE SCIENCES N.V.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

ATAI Life Sciences N.V. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. In no event shall the Company be required to award an additional payment if the restated or accurate financial results would have resulted in a higher Incentive-Based Compensation payment. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation or forfeit by the Company or an affiliate of the Company of Incentive-Based

Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other current or future compensation payable by the Company or an affiliate of the Company to such person.

Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person. The Committee need not utilize the same method of recovery for all Officers or with respect to all types of Incentive-Based Compensation. Notwithstanding the foregoing, the Company makes no guarantee as to the compliance of the recovery with Section 409A of the Internal Revenue Code and shall have no liability with respect thereto.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Supervisory Board of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability; Successors

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company. This Policy shall be binding and enforceable against all Officers and, to the extent required or permitted by the Applicable Rules, their beneficiaries, heirs, executors, administrators or other legal representatives.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Acknowledgment.

To the extent required by the Committee, each Officer shall be required to sign and return to the Company the acknowledgement form attached hereto as Exhibit A pursuant to which such Officer will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Officer will be fully bound by, and must comply with, the Policy, whether or not such Officer has executed and returned such acknowledgment form to the Company.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the Compensation Committee of the Board, provided, that, for purposes of determining whether recovery of Incentive-Based Compensation that is Erroneously Awarded Compensation would be Impractiable, "Committee" shall mean the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return. Financial reporting measures may include "non-GAAP/IFRS financial measures" as well as other measures, metrics and ratios that are not GAAP/IFRS measures. For the avoidance of doubt, a financial reporting measure need not be presented in the Company's financial statements or included in a filing with the Securities and Exchange Commission.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct expenses paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company has (i) made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after such person began

service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the Company has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves or served as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.

EXHIBIT A

ATAI LIFE SCIENCES N.V.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

FORM OF OFFICER ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the ATAI Life Sciences N.V. Policy for Recovery of Erroneously Awarded Compensation, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with ATAI Life Sciences N.V. (the "***Company***") or its affiliates to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

As a condition of receiving Incentive-Based Compensation from the Company or its affiliates, the undersigned agrees that any Incentive-Based Compensation received on or after October 2, 2023 is subject to recovery pursuant to the terms of the Policy, and further agrees to abide by the terms of the Policy including, without limitation, by returning any Erroneously Awarded Compensation to the Company or the applicable affiliate reasonably promptly to the extent required by, and in a manner permitted by, the Policy, as determined by the Committee in its sole discretion.

In the event that the Committee (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company or any of its affiliates pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification in connection with any enforcement of the Policy by the Company or any of its affiliates.

Agreed and Acknowledged:

____

Name: __

Title: ___

Date: ___