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, 2022

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 Exchange 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, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $411.1 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 15, 2023, the registrant had 166,010,476 common shares, par value €0.10 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2023 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2022, 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, 2022 (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 limitiation 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 Hercules Capital, Inc. 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 subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including 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, 2022.

Corporate Reorganization

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. On January 11, 2021, our name was changed to ATAI Life Sciences B.V. In April 2021, all of the outstanding shares in ATAI Life Sciences AG were contributed and transferred to ATAI Life Sciences B.V. in a capital increase in exchange for newly issued common shares of ATAI Life Sciences B.V. and, as a result, ATAI Life Sciences AG became a wholly owned subsidiary of ATAI Life Sciences B.V. and the former shareholders of ATAI Life Sciences AG became the shareholders of ATAI Life Sciences B.V. In connection with such exchange, the common share in ATAI Life Sciences B.V. held by Apeiron Investment Group Ltd. was cancelled (*ingetrokken*). On June 7, 2021, the existing issued shares of ATAI Life Sciences B.V. were split applying a ratio of 1.6 to one, and the nominal value was reduced to €0.10. 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.

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 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 development efforts;
- 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;
- 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 be more profitable or for which there is a greater likelihood of success, which may adversely affect our future revenues;
- 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;
- 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;
- 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 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;
- Our business is subject to economic, political, regulatory and other risks associated with international operations; 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, as well as the emergence of therapies that previously may have been overlooked or underused.

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.

Our Model and Strategy

We have a team of experienced drug discoverers, developers and innovators working to heal mental health disorders. We operate a decentralized model to enable scalable drug or technological development at our atai companies. Our atai companies drive development of programs that 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 programs in a cost-efficient manner. 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.

This model enables 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.

An example of a value-capturing event includes geography-specific collaboration agreements, such as the “Otsuka Agreement”, pursuant to which one of our atai companies, Perception Neurosciences, received a $20.0 million upfront payment and Otsuka was granted exclusive rights to develop and commercialize arketamine, known as PCN-101, in Japan.

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. Our pipeline also includes nonpsychedelic compounds. 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 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, including Introspect Digital Therapeutics, as well as IntelGenx Technologies, a strategic investment of ours. While many of these technologies remain in early stage development, we are currently investigating the IntelGenx Technologies’ oral thin film ("OTF") drug delivery system in a Phase 1 clinical trial as a novel formulation of Viridia's VLS-01.

In addition, we also conduct early-stage drug discovery through our discovery platform companies. 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.

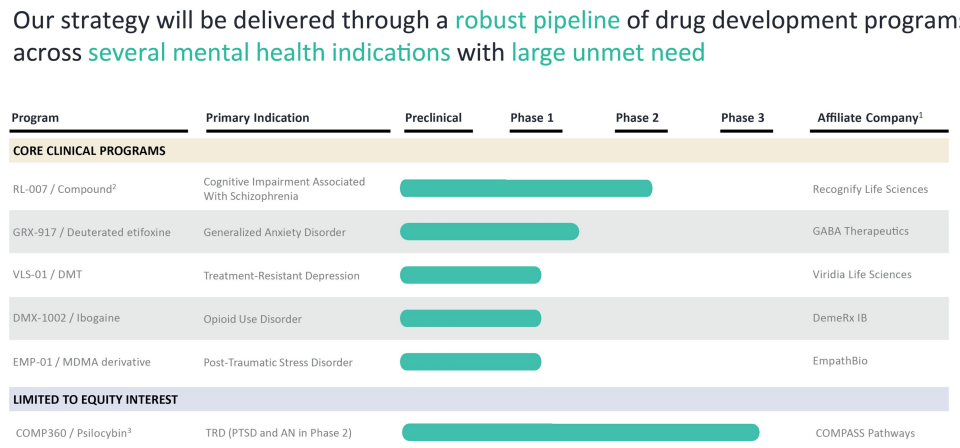
Our Ownership in COMPASS

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. Topline pivotal data for the first and second trials are expected in the summer of 2024 and mid-2025, respectively.

As of December 31, 2022, we beneficially owned 9,565,774 shares representing a 22.4% 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.

Our Key Clinical Programs

Our pipeline currently consists of therapeutic candidates across multiple neuropsychiatric indications including depression, cognitive impairment associated with schizophrenia ("CIAS"), anxiety, opioid use disorders ("OUD"), and post-traumatic stress disorder ("PTSD"). We believe there may be additional indications with potential for treatment using psychedelic therapeutics, including obsessive-compulsive disorder, attention deficit hyperactivity disorder and eating disorders, each of which we believe represent areas of unmet medical need. The table below summarizes the status of our product candidate portfolio as of the date of this Form 10-K.



Note: DMT = N,N-dimethyltryptamine; MDMA = 3,4-Methylenedioxymethamphetamine

(1)Recognify and DemeRx IB are variable interest entities; GABA is a non-consolidated VIE with operational involvement through MSA model; EmpathBio and Viridia are wholly-owned subsidiaries; COMPASS Pathways is a non-controlling equity interest.

(2)RL-007 compound is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propan-1-one(L)-(+) tartrate salts

(3)Developing COMP360, a formulation of psilocybin administered with psychological support from specially trained therapists

The following details our lead clinical programs, including related prior evidence in humans based on third-party clinical trials or studies, recent advancements, and upcoming milestones, as applicable.

RL-007 (Recognify Life Sciences)

•**Product Concept:** RL-007 is an orally bioavailable compound that has exhibited neuroplasticity enhancing effects in vitro and ex vivo as well as pro-cognitive, anxiolytic, and antinociceptive effects in non-clinical studies. 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 Phase 1 and Phase 2 clinical trials. In four clinical studies in which cognition was assessed, including two Phase 1 and two Phase 2 clinical studies, the compound has demonstrated pro-cognitive effects. 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.

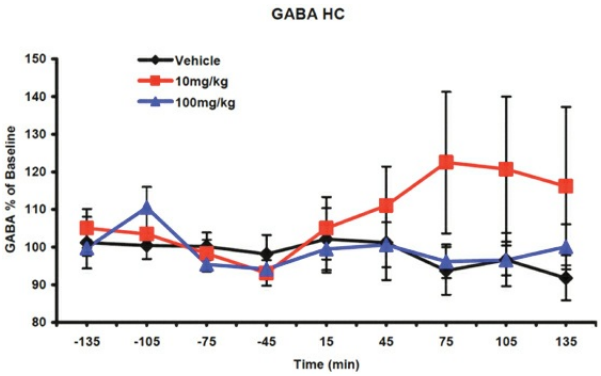
While antipsychotics are most commonly used to treat the psychotic symptoms of schizophrenia, they fail to address the cognitive and negative symptoms of this condition. Moreover, there are no drugs approved for the specific treatment of CIAS.

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

Non-Clinical

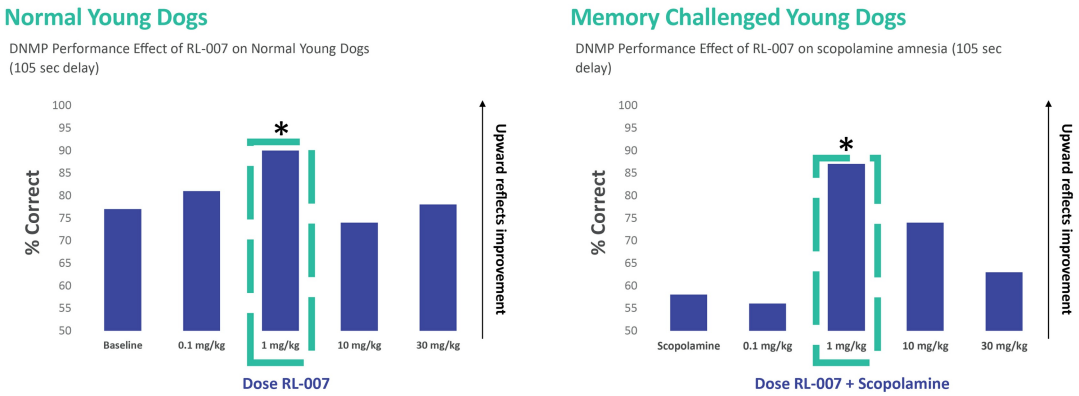
RL-007 has been shown to be active in a broad range of non-clinical models, consistently exhibiting pro-cognitive, anxiolytic, antinociceptive and anticonvulsant effects.

Although the precise molecular target and mechanism of action for RL-007 has not been elucidated, studies with co-delivered antagonists suggest that RL-007 modulates both inhibitory and excitatory neuronal signaling through the γ-aminobutyric acid $GABA_B$ and α4β2 nicotinic receptor complexes. In addition, a microdialysis study has demonstrated that the oral administration of an intermediate (10 mg/kg) but not high (100 mg/kg) dose of RL-007 to rats results in increased extracellular concentrations of GABA in the ventral hippocampus (a brain structure understood to play an important role in memory).



In contrast to other compounds that increase extracellular concentrations of GABA or that are agonists of $GABA_B$ 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.

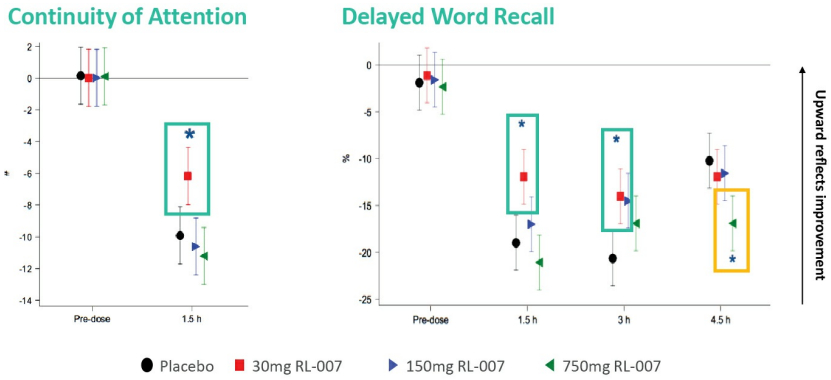
Studies in several species have demonstrated that RL-007 can reverse the effects of scopolamine, a muscarinic antagonist that induces temporary cognitive impairment, and can also improve performance in complex memory tasks in aged animals, bringing their performance to a comparable level as young animals.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

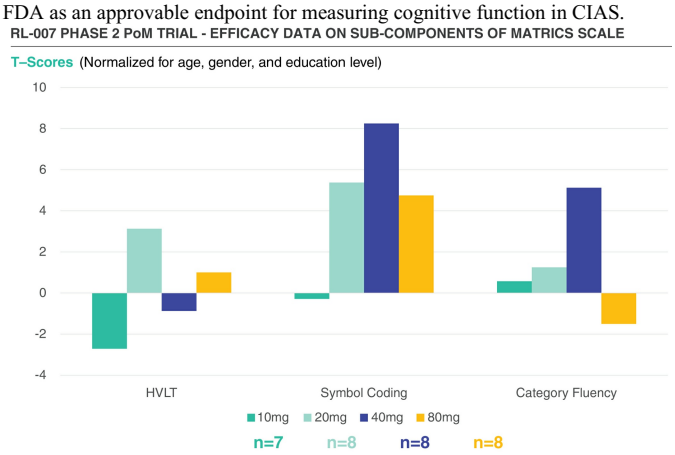
Phase 2 Study in Diabetic Peripheral Neuropathic Pain (DPNP)

A third-party conducted a Phase 2 study that enrolled 181 patients with DPNP in a double-blind, randomized, placebo-controlled study. 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 the cohort receiving RL-007 at the lower dose (40 mg TID for one week, then 80 mg TID for three weeks), significant improvement in immediate and delayed word recall was observed compared with placebo, suggesting that RL-007 may be associated with cognitive enhancement. 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 a inverted-U 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 neurocognitive composite score at 6-weeks. We anticipate reporting top-line results from this study in the second half of 2024.

GRX-917 (deuterated Etifoxine -GABA Therapeutics)

•**Product 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 and 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 pharmacokinetic 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, pharmacokinetics and pharmacodynamics (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 pharmacokinetics 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, we announced positive final results from the Phase 1 study. GRX-917 was well-tolerated in the single ascending dose and multiple ascending dose cohorts. Additionally, the data confirmed an improved pharmacokinetic 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.

Regulatory Authorities Pharmacovigilance assessments of Etifoxine

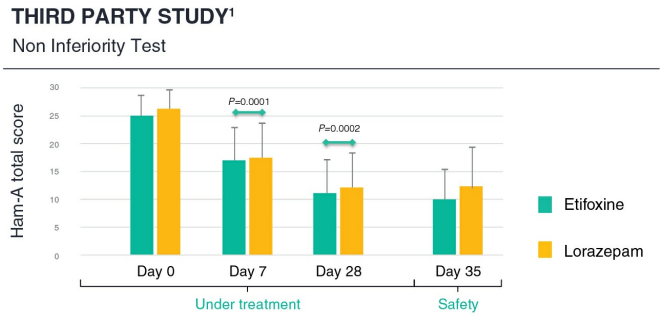
An analysis of the safety profile of etifoxine (2000-2012) was completed by the French National Agency for the Safety of Medicines and Health Products ("ANSM") France showed that the profile of Adverse Drug Reaction (ADR) is globally similar to that expected and there were no new safety data regarding 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 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:** In March 2023, we updated the GRX-917 development plan to proceed with a Phase 2 study in patients with an anxiety disorder. The updated plan is anticipated to generate the robust clinical data needed to inform potential registrational studies. We expect to provide more details on the clinical development plan upon initiation of the study.

Viridia Life Sciences: VLS-01 (N,N-Dimethyltryptamine; ("DMT")) for TRD

•**Product Concept:** VLS-01 is an OTF formulation of DMT. Pharmacologically, DMT is a partial agonist of the 5-HT 1A/2A/2C receptors, characterized by an intrinsically short duration of psychedelic effect, 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 (MDD). VLS-01's OTF formulation may eliminate the need for IV infusion.

•**Disease Overview:** 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.

We are initially focused on a subtype of MDD, referred to as TRD. 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 that 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 that 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 that have attempted suicide may be as high as 30%, approximately a seven-fold increase compared to people with MDD that 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.

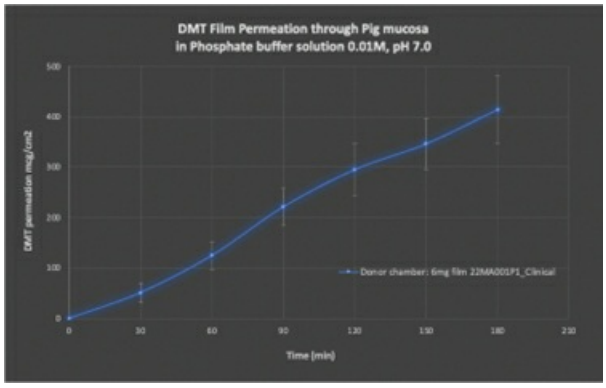
•**Prior Evidence – Non-Clinical and Clinical Data:**

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 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:** A Phase 1 open-label, single ascending dose, two-part trial of VLS-01 was initiated in October of 2022. The study compares the safety, tolerability, and pharmacokinetics of VLS-01 administered via IV infusion and oral

routes, as well as the pharmacodynamics of DMT using qEEG and other measures. We expect topline results for the Phase 1 study during the first half of 2023.

DemeRx IB: DMX-1002 (ibogaine) for OUD

•**Product Concept:** DMX-1002 is an oral formulation of ibogaine, a cholinergic, glutamatergic and monoaminergic receptor modulator that is a naturally occurring psychedelic product isolated from a West African shrub, which we are developing for the treatment of OUD.

•**Disease Overview:** SUDs 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.

For many patients, pain relief and substance use disorders are fundamentally linked, given that the use of opioids to manage acute pain can lead to drug dependence. While opioids are indeed effective for most forms of acute pain, they are associated with a variety of adverse effects, including risk of addiction and respiratory depression, the latter being the main cause of death among opioid users. Of individuals prescribed at least one day of opioids, 6% are still taking them one year later. Moreover, it is estimated that 8% to 12% of individuals prescribed opioids for chronic pain ultimately develop OUD.

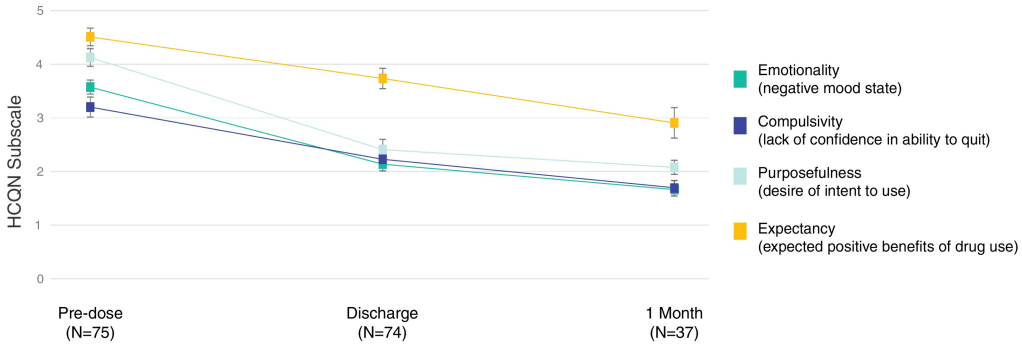
There are limited pharmacological agents available to treat OUD, with the current options divided into two classes: (i) synthetic opioid receptor full or partial agonists, such as methadone and buprenorphine, respectively, and (ii) opioid antagonists, such as naltrexone and naloxone. These therapies 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 Evidence – Clinical Data:** 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, or 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)

•**Recent Advancements:** DMX-1002 is being tested in an ongoing Phase 1/2 trial to evaluate its safety, tolerability, pharmacokinetics, and efficacy in recreational drug users and healthy volunteers, to help inform future studies in patients with OUD. We expect initial data from the Phase 1 study in the first half of 2023.

EmpathBio: EMP-01 (MDMA derivative) for PTSD

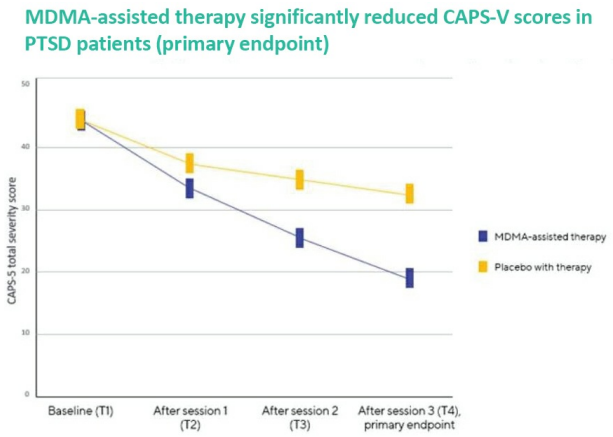
•**Product Concept:** EMP-01 is an oral formulation of an MDMA derivative being developed for the treatment of PTSD. We are developing EMP-01 as a better tolerated alternative to racemic MDMA for this indication.

•**Disease Overview:** PTSD is a psychiatric disorder that affects approximately 4% of the global population and over 8% of the U.S. population. PTSD symptoms include recurring and intrusive negative thoughts, mood and memories, reduced cognitive abilities, hyperarousal, reactivity and avoidance that persist for longer periods than a month after experiencing a traumatic event. Overall reduction in quality of life is common in individuals with PTSD leading to disability and the further manifestation of other comorbidities such as obesity, hypertension, concomitant mental health conditions and suicidality.

The current first line treatment for PTSD is the use of trauma-focused psychotherapy, but access to these psychotherapies is typically difficult, and not all with PTSD respond to psychotherapy alone. Similarly, medication-only treatment is ineffective in controlling PTSD symptoms in as many as 40% to 60% of patients, and many of these medications commonly produce problematic side effects. Given the issues with access to trauma-focused psychotherapy and ineffectiveness of current pharmacotherapy, PTSD is a mental health disorder of high unmet medical need. We believe novel interventions are needed to better treat PTSD.

•**Prior Evidence - Clinical Data:** In a meta-analysis of 21 third-party trials of other formulations of MDMA combined with psychotherapy for the treatment of PTSD, the benefits of such treatment were statistically significant versus placebo or active placebo-assisted therapy alone.

In addition, a recent third-party randomized, double-blind, placebo-controlled phase 3 study of 90 patients with severe PTSD showed a statistically significant reduction in PTSD symptoms in the MDMA-assisted psychotherapy group versus placebo.



Note: Change in CAPS-V total severity score from T1 to T4 ($P < 0.0001$, $d = 0.91$, $n = 89$ (MDMA $n = 46$)), as a measure of the primary outcome. Primary analysis was completed using least square means from a mixed model repeated measure (MMRM) analysis model; (n=90)

•**Recent Advancements:** In September 2022, after having received approvals from Medsafe, the New Zealand Medicines and Medical Devices Safety Authority and the Health and Disability Ethics Committees, we initiated our Phase 1 single ascending dose trial to assess the safety and tolerability of orally administered EMP-01 in up to 32 healthy volunteers. This trial will also incorporate our digital therapeutics technology, with the technology used to prepare subjects prior to dosing. We expect initial results for the Phase 1 study in the second half of 2023.

Our Other Clinical Programs

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

•**Product 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 conjunction with the Phase 2a study results of PCN-101, we announced that we would further evaluate the data and work to determine next steps for the program. We will continue to support Perception's development of

PCN-101 through an IV-to-subcutaneous bridging study, which is currently on-track to be completed in the middle of 2023. In parallel, we are continuing to work with Perception Neuroscience to explore strategic partnership options.

Kures: KUR-101(deuterated mitragynine) for OUD

•**Product Concept:** KUR-101 is a formulation of deuterated mitragynine that is being developed for the treatment of OUD. Mitragynine is the active component of the leaves of the kratom tree (Mitragnyna speciosa).

•**Prior Evidence:** Kratom has a long history of traditional medicine use as an analgesic in parts of Southeast Asia, and its use in the United States has increased in recent years, particularly amongst individuals seeking to reduce prescription opioid consumption or manage opioid withdrawal symptoms. Published third-party human data involving isolated mitragynine are limited, but recent mechanistic insights suggest that this compound may be well-suited for the medically assisted therapy of OUD.

•**Recent Advancements:** In December 2022, we announced results from the Phase 1 study of KUR-101 in healthy volunteers. This two-part trial was designed to assess the safety, tolerability, pharmacokinetics, and analgesic activity of KUR-101. Overall, KUR-101 failed to show a greater therapeutic index—the ratio of analgesic activity to respiratory depression—compared to oxycodone. Considering the totality of data generated to date, we are working with Kures Therapeutics to explore external funding and strategic partnership options.

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, Relmada Therapeutics, Novartis, GH Research, 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 Karuna Therapeutics, Sunovion, Newron Pharmaceuticals, Reviva Pharmaceuticals and Acadia 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, Mindmed, Bionomics, as well as the non-profit medical research organization MAPS.

Intellectual Property

Overview of our Intellectual Property

Our success depends in large 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 the date of this Form 10-K, our intellectual property portfolio includes 32 issued U.S. patents, 273 issued non-U.S. patents, 37 pending U.S. patent applications, 65 pending non-U.S. patent applications, 26 pending U.S. provisional applications, and 27 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.

COMPANY	Lead Compound	Issued		Pending	
		MoT	CoM	MoT	CoM
Perception	PCN-101	✓		✓	✓
Recognify	RL-007	✓	✓	✓	✓
DemeRx IB	DMX-1002	✓		✓	
Kures	KUR-001			✓	✓
GABA	GRX-917	✓	✓		✓
EmpathBio	EMP-01			✓	✓
Revixia Life Sciences	RLS-01			✓	✓
Viridia Life Sciences	VLS-01	✓	✓		
PsyProtix	Pre-lead			✓	✓
Entheogenix	Pre-lead			✓	✓
Psyber	N/A				
Introspect	N/A				

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

A description of our patents as of the date of this Form 10-K follows below:

Perception Neuroscience (PCN-101)

Perception Neuroscience in-licenses three issued U.S. patents, three foreign issued patents in Japan and 2 foreign issued patents in Europe and Canada, four U.S. pending patent applications and 15 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 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 U.S. provisional patent 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.

Recognify (RL-007)

Recognify in-licenses ten issued U.S. patents and 39 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.

DemeRx IB (DMX-1002)

DemeRx IB owns five issued U.S. patents and two foreign issued patents in Europe and Australia, four U.S. pending patent applications, and four foreign pending patent applications in Australia, Europe, Hong Kong and Canada covering methods of treatment using ibogaine (DMX-1002). 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 Life Sciences AG 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.

GABA Therapeutics (GRX-917)

GABA Therapeutics owns two issued U.S. patents, one U.S. pending patent application, eleven issued foreign patents in Australia, Brazil, Canada, China, Europe, Mexico, Israel, Japan, Republic of Korea and Mexico and three foreign pending patent applications in India and Japan, covering the pharmaceutical composition and corresponding methods of use of the deuterated analogs of etifoxine (GRX-917). GABA Therapeutics owns one U.S. provisional patent application, covering methods of administering 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.

Viridia Life Sciences (VLS-01)

Atai Life Sciences AG owns one issued U.S. patent, three U.S. pending patent applications and two PCT patent applications, covering (i) DMT compositions exhibiting unique PK profiles following administration and (ii) new DMT salts and polymorphic forms, including DMT succinate (VLS-01). 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. Atai Life Sciences AG owns four U.S. pending patent applications, three PCT patent applications and two U.S. provisional patent applications, 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 2043, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Atai Life Sciences AG owns one U.S. provisional patent application, covering polymorphic forms of DMT. Any patents issuing from this pending patent application, if granted, are expected to expire in 2043, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EmpathBio (EMP-01)

Atai Life Sciences AG owns six U.S. pending patent applications, five 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 Life Sciences AG owns one U.S. provisional patent application, covering salts of R-MDMA and polymorphic forms. Any patents issuing from this pending patent application, if granted, are expected to expire in 2043, exclusive of possible patent term adjustments or extensions or other forms of exclusivity. Atai Life Sciences AG owns three U.S. provisional patent applications, covering salts of R-MDMA, the synthesis of R-MDMA and S-MDMA, and uses of MDMA for treating stress related disorders. Any patents issuing from these pending patent applications, if granted, are expected to expire in 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, 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 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, and of selected clinical investigation sites to assess compliance with GCP requirements;

•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, we 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, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; 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 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 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 statistically significant 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 approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

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, such as with accelerated approval drugs, FDA may mandate the performance of Phase 4 trials. 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. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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, 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.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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 it 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 an additional pivotal Phase 3 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 Phase 4 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 these 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 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 and accelerated approval. 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, 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. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials 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 indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication 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 an indication 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 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 marketing 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.

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, 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-labelling 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 Conference on Harmonization, 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 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 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 marketing authorization, or 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.

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, unless additional Congressional action is taken. 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, currently set at 100% of a drug’s average

manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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. 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 the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This 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 providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The Regulation 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 most potential impact for patients, joint scientific consultations.

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 (e.g., Section 5 of the Federal Trade Commission Act, or the FTC Act), 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. For example, the General Data Protection Regulation, or GDPR, imposes strict requirements for processing the personal data of individuals within the European Economic Area. 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 or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision, and remains under review by the Commission during this period. In September 2021, the United Kingdom government launched a consultation on its proposals for wide-ranging reform of United Kingdom data protection laws following Brexit. There is a risk that any material changes which are made to the United Kingdom data protection regime could result in the Commission reviewing the United Kingdom adequacy decision, and the United Kingdom losing its adequacy decision if the Commission deems the United Kingdom to no longer provide adequate protection for personal 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. See “Risk Factors—Risks Related to Commercialization—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."

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 a healing mental health disorders so that everyone, everywhere can live a more fulfilled life.

As of December 31, 2022, we had 119 full-time employees and 23 contractors or consultants doing regular work for the company. Our subsidiary companies had 14 additional full-time employees. Of our full-time employees, 64 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 half of our employees are located in the U.S.; the remainder are split between the UK and Germany, with one employee in the Netherlands.

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. As of March 15, 2023, we had 91 full-time employees and 14 additional full-time employees employed by our subsidiary companies. Of these full-time employees, 53 focus on research and development either directly or through one of our subsidiaries. Additionally, we had 18 contractors or consultants doing regular work for the company.

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

We have an in-house talent acquisition capability to support atai and its subsidiaries in hiring the right talent at the right time. This team of experienced recruiters works closely with hiring managers to understand the required skills and capabilities for an open role, and then supports the interview process and evaluation of candidates. We strive to hire top talent, and therefore need a high-quality recruiting process and candidate experience. We are consistently looking at new opportunities and avenues to recruit talented individuals.

We are committed to attracting and retaining top performing team members. We focus on creating a dynamic, vibrant, values-based culture that allow 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. At the end of each cycle, all employees are given a performance rating, which informs decisions regarding promotions, salary adjustments, and annual equity grants.

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 on our website at https://ir.atai.life/corporate-governance/governance-overview.

Total Rewards and Employee Engagement

To attract and retain top talent, we offer a competitive total rewards package. We target pay between the 50th and 75th percentile of market, based on Aon Radford data, and employee stock option grants at the 50th 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 semi-annually 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 volunteerism. 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.

As part of our Diversity, Equity and Inclusion efforts, we have launched a 1-1 coaching offering for diverse employees. We have also formed a "women of atai" network and intend to roll out additional initiatives in 2023.

Hybrid office culture

As of December 31, 2022, we had offices in Berlin, London, New York, and San Diego. We aim to foster a hybrid culture where most employees are in the office two or three days per week, but with the option to work in office more. 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.

COVID-19 Business Update

The COVID-19 pandemic has continued to present global public health and economic challenges. Although some research and development timelines have been impacted by delays related to the COVID-19 pandemic, the Company has not experienced material financial impacts on its business and operations as a result. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, the success or failure of ongoing vaccination programs worldwide, the emergence and spread of additional variants of COVID-19, as well as the overall impact on local, regional, national and international markets and the global economy. For a discussion of the risks related to COVID-19 and impact to the Company's business and operations, including its research and development programs and related clinical trials, refer to the section titled "Risk Factors" in Part I, Item 1A.

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 risks and uncertainties described below are not the only ones we face. Additional risk and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. 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, 2022 and December 31, 2021 was $152.4 million and $167.8 million, respectively. We have no products that are approved for commercial sale and have not generated any commercial product revenue. We have financed operations solely through the sale of equity securities and convertible 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, 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 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 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.

We expect that our existing cash and cash equivalents and short-term investment securities as of December 31, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date the consolidated financial statements are issued. However, our operating plan may change as a result of many factors 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 activities, which may adversely affect our ability to develop and commercialize product candidates that 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 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;

- 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, the COVID-19 pandemic and the related U.S. and global economic impact 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 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 pipeline, we expect to finance our future cash needs through a combination of public and private equity or debt financings, strategic partnerships, sales of assets and alliances and licensing arrangements. 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 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.

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 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 necessarily 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.

Under certain of our investment arrangements, if we fail to make a milestone payment when due, our ownership percentage may fall below 50% of that entity.

Under our investment arrangements with DemeRx IB, Recognify Life Sciences, PsyProtix, Psyber, InnarisBio and TryptageniX, if we fail to make a milestone payment when due, we could lose our majority interest in DemeRx IB, Recognify Life Sciences, PsyProtix, Psyber, InnarisBio or TryptageniX. In order to maintain our equity ownership in these companies, we will need to make $15.2 million in remaining aggregate milestone payments upon the achievement of certain development milestones.

In December 2019, we executed a promissory note payable to DemeRx IB whereby we agreed, under a contribution agreement and a Series A Preferred Stock Purchase Agreement, to make aggregate payments to DemeRx IB of up to $17.0 million upon the achievement of specified clinical and regulatory milestones. In connection with this promissory note, we pledged and assigned to DemeRx IB a portion of the Series A Preferred Stock of DemeRx IB as security under the promissory note. In the event of default, a pro rata portion of these pledged shares will automatically be surrendered and be deemed forfeited and canceled and could result in us losing control of DemeRx IB's board of directors and our controlling financial interest in DemeRx IB. To date, we have made aggregate payments of $17.0 million in connection with the promissory note.

In November 2020, we acquired Series A preferred stock of Recognify Life Sciences pursuant to a Series A Preferred Stock Purchase Agreement, and, as amended, we agreed to make aggregate payments to Recognify Life Sciences of up to $20.0 million upon the achievement of specified clinical and regulatory milestones to complete the purchase of the shares and provide additional funding. In connection with this agreement to provide additional funding, Recognify Life Sciences issued the Series A preferred shares to us but held the shares in an escrow account, with the shares to be released upon receipt of our milestone payments. In the event of default, a pro rata portion of the shares held in escrow will automatically be surrendered and be deemed forfeited and canceled, and could result in us losing control of Recognify Life Sciences' board of directors and our controlling financial interest in Recognify Life Sciences. To date, we have made aggregate payments of $14.5 million.

In February 2021, we acquired Series A preferred stock of PsyProtix pursuant to a Series A Preferred Stock Purchase Agreement, and we agreed to make aggregate payments to PsyProtix of up to $4.9 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding. In connection with this agreement to provide additional funding, PsyProtix issued the Series A preferred shares to us but held the shares in an escrow account, with the shares to be released upon receipt of our milestone payments. In the event of default, a pro rata portion of the shares held in escrow will automatically be surrendered and be deemed forfeited and canceled, and could result in us losing control of PsyProtix's board of directors and our controlling financial interest in PsyProtix. To date, we have made aggregate payments of $0.6 million.

In February 2021, we acquired Series A preferred stock of Psyber pursuant to a Series A Preferred Stock Purchase Agreement, and we agreed to make aggregate payments to Psyber of up to $1.8 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding. In connection with this agreement to provide additional funding, Psyber issued the Series A preferred shares to us but held the shares in an escrow account, with the shares to be released upon receipt of our milestone payments. In the event of default, a pro rata portion of the shares held in escrow will automatically be surrendered and be deemed forfeited and canceled, and could result in us losing control of Psyber's board of directors and our controlling financial interest in Psyber. To date, we have made aggregate payments of $1.4 million.

In March 2021, we acquired Series A preferred stock of InnarisBio pursuant to a Series A Preferred Stock Purchase Agreement, and we agreed to make aggregate payments to InnarisBio of up to $4.0 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding. In connection with this agreement to provide additional funding, InnarisBio issued the Series A preferred shares to us but held the shares in an escrow account, with the shares to be released upon receipt of our milestone payments. In the event of default, a pro rata portion of the shares held in escrow will automatically be surrendered and be deemed forfeited and canceled, and could result in us losing control of InnarisBio's board of directors and our controlling financial interest in InnarisBio. To date, we have made aggregate payments of $1.9 million.

In December 2021, we acquired Series A preferred stock of TryptageniX pursuant to a Series A Preferred Stock Purchase Agreement, and we agreed to make aggregate payments to TryptageniX of up to $5.0 million upon the achievement of development milestones to complete the purchase of the shares and provide additional funding. In connection with this agreement to provide additional funding, TryptageniX issued the Series A preferred shares to us but held the shares in an escrow account, with the shares to be released upon receipt of our

milestone payments. In the event of default, a pro rata portion of the shares held in escrow will automatically be surrendered and be deemed forfeited and canceled, and could result in us losing control of TryptageniX's board of directors and our controlling financial interest in TryptageniX. To date, we have made aggregate payments of $2.2 million.

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

Market conditions impacting financial institutions could impact our ability to access some or all of our cash, cash equivalents and short-term investments, and we may be unable to obtain alternative funding when and as needed and on acceptable terms, if at all. The performance of the capital markets affects the values of funds that are held in short-term investments. These assets are subject to market fluctuations and various developments, including, without limitation, rating agency downgrades that may impair their value. Further, a bankruptcy of one of the banks in which or through which we hold or invest our cash reserves, might prevent us from accessing all or a portion of that cash for an uncertain period of time if at all. For example, we maintain cash balances at various third-party financial institutions in excess of the $250,000 Federal Deposit Insurance Corporation ("FDIC") insurance limit. Widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of the FDIC insurance program. There is no guarantee that the Federal Reserve Board, the U.S. Treasury Department and the FDIC will provide access to uninsured funds in the future in the event of the closure of any banks or financial institutions in a timely fashion or at all.

If we do not effectively diversify our bank deposits and investment portfolio, the value and liquidity of our investments may fluctuate substantially which could affect our access to capital and results of operations in a material way. Furthermore, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements directly face liquidity constraints or failures. Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our results of operations and liquidity.

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 COMPASS, a large proportion of our overall value may at any time reside in our ownership interest of COMPASS. Our interest in COMPASS may also be reduced to the extent COMPASS raises capital from third-party investors. Accordingly, any material adverse impact on the value of the business of a subsidiary or a clinical program, and on the value of COMPASS, 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 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 terms and are uncertain. Similarly, investments in companies that are in the development stage 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 Non-Controlled 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 are considered relatively new and novel, 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, and this 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, DemeRx is 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, Kures is developing KUR-101, a derivative of mitragynine, for the treatment of substance use disorder. 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.

In addition, responses by the United States, state 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 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.

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 be more profitable or for which there is 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 challenging decisions regarding the allocation of capital and resources across our businesses. For example, in November 2022 we made a decision to deconsolidate Neuronasal to further

focus our capital allocation towards generating meaningful clinical readouts in the near-term and to optimize our operational efficiency. In addition, 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 prove to have greater commercial potential than our current or future development programs and product candidates. In addition, our decisions concerning the allocation of research, collaboration, management and financial resources toward particular programs or product candidates may not lead to the development of viable commercial product candidates, and may divert resources, including personnel, away from more advantageous opportunities or from our other current programs. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product candidates and development programs could also prove not to be optimal and could cause us to miss valuable opportunities with no resulting benefit. If our assessment of the market potential of our product candidates or trends in the pharmaceutical or biotechnology industries proves to be inaccurate, our business, financial condition and results of operations could be materially adversely affected.

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

Due to the international scope of our operations, our assets and cash flows are and will continue to be influenced by movements in exchange rates of several currencies, particularly the U.S. dollar and the euro. Our reporting currency and our functional currency is primarily the U.S. dollar, but many of our operating expenses are paid in euro. We also regularly acquire services, consumables and materials in euro, and potential future revenue may be derived from Europe. 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, recently evolved. 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 Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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 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 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 practices 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board, or DSMB, 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 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, purity, efficacy 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.

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 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.

Further, successful and timely enrollment in clinical trials may be adversely affected by global health factors, including, among other things, pandemics such as COVID-19, such as:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the limitation of available participants for our trials and a decrease in enrollment of our trials;
- the inability of patients, therapists or physicians to come to hospitals and universities to participate in our trials, leading to delays and increased costs;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring and patient preparation and integration sessions;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

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, 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, or SAEs, 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 receives 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 receives regulatory approval, it 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 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, 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 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 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 topline 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 topline 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. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline 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, topline, 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.

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 our current or future product candidates. If the third-party therapy sites fail to recruit, train and retain 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.

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 inability to develop efficient manufacturing processes, equipment malfunctions, facility contamination, raw material shortages or contamination, 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.

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 FDA's Center for Drug Evaluation and Research and 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.

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.

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 the 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.

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 product 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 permits 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 distribution services, the profitability of product revenue may be lower than if we were to market and sell 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.

Our product candidates contain controlled substances, including psychedelic substances, which are subject to strict legal requirements in certain jurisdictions where we will produce and sell our products. Certain jurisdictions may not allow the use or production of the substances included in our products, 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 drugs 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, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), 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 collaborators. In addition, 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, 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, or CCPA, which creates individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Further, a new privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA significantly amends the CCPA and will create additional obligations relating to personal information that went into effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. Compliance with U.S. and international 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. In July 2020, the Court of Justice of the European Union, or CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield. The CJEU further noted that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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 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 will pay 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 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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. 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, and Praxis Precision Medicine; CIAS, including from Boehringer Ingelheim, Biogen, Karuna Therapeutics, Minerva Biosciences, Sunovion Pharmaceuticals, and Takeda Pharmaceuticals Vanda and Novartis; SUD, including from BioXcel, Opiant and Intra-Cellular Therapies; anxiety, including from VistaGen Therapeutics, Bionomics and Arvelle

Therapeutics; mTBI, including from SanBio, Vasopharm, Levolta Pharmaceuticals, Oxeia, Otsuka and Athersys; 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 are 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, which may include risks that:

- 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 comply with GCPs. We are also required to register certain clinical trials and post the results of 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.

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, products, or necessary quantities of such materials on time or at an acceptable cost.

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 they 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 and other comparable foreign authorities pursuant to inspections that will be conducted after we submit an NDA, or other marketing application to the FDA and other comparable foreign 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 or others, 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 pass 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 or MAA variation, or equivalent foreign regulatory filing is also required, which could result in further delay. Similarly, for 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, geo-political actions in the United States and in foreign countries 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.

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.

Further, in Europe, a new unitary patent system takes 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, 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 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 expand our organization and may experience difficulties in managing this potential growth, which could disrupt our operations.

As we mature, we may expand our full-time employee base and hire more consultants and contractors. Our management has, 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 growth activities. We may not be able to effectively manage a potential expansion 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. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates or opportunistic business activities. If our management is unable to effectively manage our potential growth, our expenses may increase more than expected, 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 growth.

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 therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates. 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, 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 business. If we were to face any employment-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.

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.

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 the rate of unemployment (including as a result of the ongoing COVID-19 pandemic and the overall global economic downturn), 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.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. 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 ongoing COVID-19 pandemic, current economic climate and 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, we implemented certain cost reduction efforts to reduce material spend and operating expenses. In February 2023, we also restructured our workforce and eliminated 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. 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.

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 utilize information technology, or IT, systems and networks to process, transmit and store electronic information, including but not limited to intellectual property, proprietary business information and personal information, in connection with our business activities. Our internal 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, 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, 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 intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data, and health-related information. There can be no assurance that we will be successful in preventing cyberattacks or successfully mitigating their effects.

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, in response to the ongoing COVID-19 pandemic, 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 security incidents to date, we cannot guarantee that we will not experience such incidents in the future.

Any cyberattack that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding clinical trial participants or employees, data breach or destruction or loss of data 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 of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks and the mishandling of data by our employees and third-party service providers, then our business, financial condition, results of operations and prospects could be adversely affected.

Disruptions at the FDA, the U.S. Securities and Exchange Commission, or the SEC, and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

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 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, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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.

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.

We are subject to risks related to public health crises such as the ongoing COVID-19 pandemic. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The full extent to which COVID-19 or other outbreaks, epidemics, pandemics 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.

In response to the ongoing COVID-19 pandemic, we have in the past taken, and may take in the future, temporary precautionary measures intended to help minimize the risk of the virus to our employees, including, from time to time, closing our offices and temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, delaying and changing the location of trials and discouraging employee attendance at industry events and in-person work-related meetings, all of which could negatively affect our business. The extent of the impact of the COVID-19 pandemic on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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 as a result of the COVID-19 pandemic. While supply shortages are beginning to show signs of recovery, they may nonetheless persist and cause significant and material disruptions to our supply chains and operations, and associated delays in the manufacturing and supply of our product candidates and any future therapeutic candidates. Any such supply disruptions would adversely impact 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.

The COVID-19 pandemic, or future pandemics, may also affect employees and patients involved in our clinical trials. Any negative impact the COVID-19 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. The COVID-19 pandemic has also caused significant volatility in public equity markets and disruptions to the United States and global economies, which has adversely impacted, and may continue to adversely impact, our share price and our ability to raise capital on favorable terms, or at all.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this "Risk Factors" section, such as those relating to the timing and completion of our clinical trials.

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

Natural or man-made disasters or outbreak of disease 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.

The increasing focus on environmental sustainability and social 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 other sustainability matters. We may experience pressure to make commitments relating to sustainability 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 other sustainability 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.

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, 2022, our German NOL carryforward was approximately $151.0 million. German tax law imposes certain limits on the utilization of NOLs that are carried forward or carried back to a particular year. Our ability to utilize NOLs may be further limited under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz – KStG*) and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz –*

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

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

According to an appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 1 KStG is not in line with the German constitution. In addition, our ability to utilize our NOLs and certain other tax attributes in the United States could be subject to limitation or expire unused under U.S. tax law. As of December 31, 2022, we had U.S. federal NOLs of $37.5 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.

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, 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. Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU and ratified a trade and cooperation agreement governing its future relationship with the EU, referred to as Brexit. The agreement, which was being applied provisionally from January 1, 2021 and entered into force on May 1, 2021, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the UK and the EU as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal. There can be no assurance that the uncertainty regarding Brexit will not have an adverse effect on our business.

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". The UK Government has proposed to repeal the majority of this retained EU law by the end of 2023 which may lead to further regulatory uncertainty and could result in cost increases for our business. 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 shares 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, and will continue to from time to time, experienced 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 several factors, including to 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 "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," which means the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter, 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 this prospectus and 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 income 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 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 primary control over the majority of the atai companies for purposes of Rule 3a-1 under the Investment Company Act (as described more fully below) and that none of the atai companies over which we have 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 45% tests in Rule 3a-1 of the Investment Company Act 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 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 primary control over the majority of our atai companies for purposes of Rule 3a-1 and that none of the atai companies over which we have 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 over which we have primary control for purposes of compliance with the requirements of Rule 3a-1. As a result we do not believe our interests in such atai companies will be deemed investment securities for purposes of Rule 3a-1. Accordingly, we believe that 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.

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, 2022, Apeiron held an 19.77% 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 part 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, to the extent we are considered an accelerated or large accelerated filer, 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 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. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that were previously identified were related to the design of internal controls as follows: (1) the lack of a sufficient number of trained professionals with the expertise to design, implement and execute a formal risk assessment process and formal accounting policies, procedures and controls over accounting and financial reporting to ensure the timely recording, review, and reconciliation of financial transactions while maintaining a segregation of duties; (2) the lack of formal processes and controls specific to the identification and recording of expense transactions, including

stock-based compensation, completely and accurately, and in the appropriate period; and (3) the lack of a sufficient number of trained professionals with the appropriate U.S. GAAP technical expertise to identify, evaluate and account for complex transactions and review valuation reports prepared by external specialists. As a result, we did not design and maintain formal accounting policies, processes and controls related to complex transactions necessary for an effective financial reporting process.

Subsequent to the identification of the material weaknesses, management implemented our previously disclosed remediation plan designed to remediate the material weaknesses and to enhance our overall control environment. Our remediation plan included, but was not limited to, the following measures:

•Engaged consultants to assist management in designing and implementing a formal risk assessment process.

•Formalized our accounting and financial reporting policies and the related procedures and designed and implemented controls over the timely recording, review, and reconciliation of financial transactions, including expense and stock-based compensation transactions.

•Hired additional qualified accounting personnel and implemented accounting systems to support our policies, procedures and controls, while maintaining segregation of duties amongst accounting personnel.

•Designed and implemented controls over the recording and review of technical accounting matters, application of new accounting standards, tax matters, and valuations, and engaged third parties subject to our oversight and review, as needed

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 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 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 directors and officers insurance, investor relations, 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.

For example, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our annual reports and to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for each Annual Report on Form 10-K we file with the SEC. In the future, to the extent we no longer qualify as an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we continue to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources and have engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to maintain effective internal control over financial reporting as required by Section 404. If we identify one or more material weaknesses in our internal control, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain
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Item 1B. Unresolved Staff Comments.

None.

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 London, the United Kingdom; 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.

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 15, 2023, there were 105 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

Except as disclosed in our Quarterly Report on Form 10-Q for the quarter June 30, 2022 filed with the SEC on August 15, 2022, there were no sales of unregistered equity securities during the year ended December 31, 2022.

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, as well as the emergence of therapies that previously may have been overlooked or underused.

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 $152.4 million and $167.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, our accumulated deficit was $510.2 million and $357.8 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, 2022, we had cash and cash equivalents of $190.6 million and short-term securities of $82.5 million. We believe that our existing cash and cash equivalents and short-term securities will be sufficient for us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following the filing of this Annual Report. 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. We are also evaluating potential divestiture of our equity interests in certain programs and also exploring other opportunities, including but not limited to seeking strategic partnership options, for example, with PCN-101 and KUR-101.

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 terms of the Loan Agreement, $15 million was drawn at closing, with an additional $20 million available to be drawn at our option by May 1, 2023, and thereafter, an additional $25 million available to be drawn at our option by December 15, 2023. The remaining $115 million becomes available in tranches through March 31, 2025, subject to the satisfaction of certain conditions. More information about the terms and conditions of the Loan Agreement See Note 10 to our consolidated financial statements included in this Annual Report as well as "—Liquidity and Capital Resources—Indebtedness—Hercules Term Loan."

Basis of Presentation and 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 our consolidated entities. 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. Ownership interests in consolidated entities that are held by entities other than us are reported as redeemable convertible noncontrolling interests and noncontrolling interests in our consolidated balance sheets. Losses attributed to redeemable convertible noncontrolling interests and noncontrolling interests are reported separately in our consolidated statements of operations.

Wholly owned subsidiaries and VIEs with greater than 50% ownership and deemed control are consolidated in our consolidated financial statements, and our net income (loss) is reduced for the noncontrolling interest of the VIE's share, resulting in net income (loss) attributable to atai shareholders.

Investments where we have ownership in the underlying company's equity greater than 20% and less than 50% or where we have significant influence are accounted for using the equity method. We then record losses from investments in equity method investees, net of tax, for our proportionate share of the underlying company's net results until the investment balance is adjusted to zero. If we make subsequent additional investments in that same company, we may record additional gains(losses) based on changes to our investment basis and also may record additional income(loss) in equity method investments.

Components of Our Results of Operations

Revenue

On March 11, 2021, we entered into a license and collaboration agreement (the "Otsuka Agreement"), with Otsuka Pharmaceutical Co., LTD ("Otsuka"), under which we granted exclusive rights to Otsuka to develop and commercialize certain products containing arketamine in Japan for the treatment of depression and other select indications. We received an upfront, non-refundable payment of $20.0 million in June 2021 and we are also eligible to receive up to $35.0 million if certain development and regulatory milestones are achieved and up to $66.0 million in commercial milestones upon the achievement of certain commercial sales thresholds. We are eligible to receive tiered, royalties ranging from low-teens to high-teens on net sales of licensed products subject to reduction in certain circumstances.

In March 2021, we satisfied the performance obligation related to the license upon delivery of the license and recognized the amount of $19.8 million allocated to the license as license revenue. Additionally, we recognized revenues of $0.6 million related to certain research and development services. Total license revenue of $20.4 million was recorded for the year ended December 31, 2021.

We recognized $0.2 million of license revenue for the year ended December 31, 2022. The remaining deferred revenue balance related to the Otsuka Agreement is not material as of December 31, 2022. To date, there have been no milestones achieved under the Otsuka Agreement.

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 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;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other operating costs; 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.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We have incurred increased expenses due to costs incurred to support organizational growth as part of commercial readiness activities. We also have incurred increased expenses associated with being a public company, including increased costs for audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense), Net

Interest Income

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

Change in Fair Value of Contingent Consideration Liability—Related Parties

Changes in fair value of contingent consideration liability—related parties, consists of subsequent remeasurement of our contingent consideration liability—related parties with Perception, TryptageniX and InnarisBio for which we record at fair value. See "—Liquidity and Capital Resources—Indebtedness" below for further discussion of our contingent consideration liability—related parties.

Change in Fair Value of Derivative Liability

Changes in fair value of derivative liability consists of subsequent remeasurement of our derivative liability relating to certain embedded features contained in the Perception convertible promissory notes for which we record at fair value. The Perception convertible promissory notes were converted during June 2021. See "—Liquidity and Capital Resources—Indebtedness" below for further discussion the Perception convertible promissory notes.

Change in Fair Value of Warrant Liability

Changes in fair value of warrant liability consists of subsequent remeasurement of our warrant liability relating to issued and outstanding warrants to purchase shares of Neuronasal's common stock acquired in connection with the acquisition of Neuronasal in May 2021. We deconsolidated Neuronasal in November 2022. See Note 3 in our consolidated financial statements for further discussion.

Change in Fair Value of Securities carried at Fair Value

Changes in fair value of securities consists of changes in fair value of our available for sale securities. We first purchased securities in January 2022.

Unrealized Loss on Other Investments Held at Fair Value

In May 2021, we received IntelGenx common stock, warrants and additional unit warrants for a price of approximately $12.3 million. We determined that the initial aggregate fair value is equal to the transaction price and recorded the common shares at $3.0 million, the 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 our consolidated statements of operations. Subsequently, changes in fair value of the common stock, the warrants and additional unit warrants are recorded as an unrealized loss on other investments held at fair value in the consolidated statement of operations.

Loss on Conversion of Convertible Promissory Notes

In June 2021, upon the funding of the Otsuka Agreement, the Perception convertible promissory notes were converted into Perception Series A preferred stock. The loss represents the difference between (i) carrying value including derivative liability of the Perception December 2020 Notes of $2.2 million and (ii) the fair value of Perception Series A preferred stock into which the Perception convertible promissory notes converted of $2.7 million.

Gain on Consolidation of a Variable Interest Entity

Gain on consolidation of a VIE resulted from the purchase of additional shares of Neuronasal in May 2021. The gain was calculated as the sum of the consideration paid, the fair value of the noncontrolling interest issued, the carrying value of our investments prior to consolidation, less the fair value of identifiable net assets acquired.

Gain on Deconsolidation of a Variable Interest Entity

Gain on deconsolidation of a VIE of $1.5 million was the result of removing Neuronasal assets and liabilities from our consolidated balance sheet following our change of control in Neuronasal in November 2022.

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 expense, net consists principally of interest expense and an impairment of a loan receivable. Interest expense consists primarily of interest expense incurred in connection with our term loan under the Loan Agreement entered into in August 2022. Upon closing of the Loan Agreement, Hercules issued a term loan advance in the amount of $15.0 million. See "—Liquidity and Capital Resources—Indebtedness" below for further discussion of the 2022 Term Loan Facility. Impairment of loan receivable relates to our impairment of the outstanding Neuronasal loans in connection with deconsolidation during the year ended December 31, 2022.

Benefit From (Provision For) Income Taxes

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

We regularly assess the need to record a valuation allowance against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. In assessing the realizability of deferred tax assets, 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.

In 2022, as a result of the commercial evolution of our intercompany arrangements, intercompany recharge structure, and other planning considerations, we re-evaluated our transfer pricing policies including with respect to share based compensation. As a result of the modified transfer pricing policy, the ultimate timing and recharge to our subsidiary service providers was no longer certain. As a result, it is no longer guaranteed that, or can be reasonably forecast whether, the deferred tax assets reported by these entities will reverse in the foreseeable future. The 2022 change in transfer pricing policy, taken together with our three-year cumulative loss position and decreased projected future earnings provided sufficient negative evidence that a full valuation allowance should be established against the net deferred

tax assets with respect to certain subsidiaries. Accordingly, as of December 31, 2022, we maintain a full valuation allowance against net deferred tax assets in all jurisdictions.

As of December 31, 2021, sufficient positive evidence existed for net deferred tax assets with regard to two subsidiaries in the United States and the United Kingdom and it was determined more-likely-than-not that such deferred tax assets would be realized and a valuation allowance was not established for those entities.

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. As of December 31, 2022 and December 31, 2021, we had no unrecognized tax benefits.

Gain on Dilution of Equity Method Investment

In May 2021, COMPASS completed an additional round of equity financing through the offering of 4,000,000 American Depository Shares. We participated in this financing round but did not purchase enough shares to maintain our ownership percentage. As the purchase of shares resulted in a decrease in our equity ownership percentage in COMPASS, we recorded a gain on dilution of $16.9 million for the year ended December 31, 2021.

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, IPR&D charges resulting from basis differences related to our equity method investments.

Net Loss Attributable to Redeemable Noncontrolling Interests and Noncontrolling Interests

Net loss attributable to redeemable noncontrolling interests and noncontrolling interests in our consolidated statements of operations is a result of our investments in certain of our consolidated VIEs and consists of the portion of the net loss of these consolidated entities that is not allocated to us. Net losses in consolidated VIEs are attributed to redeemable noncontrolling interests and 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 redeemable noncontrolling interests and 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, 2022 and 2021

	Year Ended December 31, 2022	2021	$ Change	% Change
	(in thousands, except percentages)			
License revenue	$ 233	$ 20,376	(20,143)	-98.9%
Operating expenses:				
Research and development	74,313	47,956	26,357	55.0%
Acquisition of in-process research and development	357	15,480	(15,123)	-97.7%
General and administrative	70,350	92,745	(22,395)	-24.1%
Total operating expenses	145,020	156,181	(11,161)	-7.1%
Loss from operations	(144,787)	(135,805)	(8,982)	6.6%
Other income (expense), net:				
Interest income	548	205	343	167.3%
Change in fair value of contingent consideration liability - related parties	1,475	173	1,302	752.6%
Change in fair value of derivative liability	—	41	(41)	-100.0%
Change in fair value of warrant liability	336	(87)	423	-486.2%
Change in fair value of securities carried at fair value	272	—	272	100.0%
Unrealized loss on other investments held at fair value	—	(12,346)	12,346	-100.0%
Loss on conversion of convertible promissory notes	—	(513)	513	-100.0%
Gain on consolidation of a variable interest entity	—	3,543	(3,543)	-100.0%
Gain on deconsolidation of a variable interest entity	1,484	—	1,484	100.0%
Foreign exchange gain, net	6,902	8,481	(1,579)	-18.6%
Other expense, net	(1,412)	(293)	(1,119)	381.9%
Total other income (expense), net	9,605	(796)	10,401	-1306.7%
Loss before income taxes	(135,182)	(136,601)	1,419	-1.0%
Benefit from (provision for) income taxes	(6,229)	3,989	(10,218)	-256.2%
Gain on dilution of equity method investment	—	16,923	(16,923)	-100.0%
Losses from investments in equity method investees, net of tax	(16,006)	(58,555)	42,549	-72.7%
Net loss	$ (157,417)	$ (174,244)	16,827	-9.7%
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(5,032)	(6,436)	1,404	-21.8%
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (152,385)	$ (167,808)	$ 15,423	-9.2%

License Revenue

License revenue was $0.2 million for the year ended December 31, 2022, which related to certain research and development expenses under the Otsuka Agreement. License revenue was $20.4 million for the year ended December 31, 2021, which primarily related to the delivery of the license to Otsuka, which occurred in March 2021.

Research and Development Expenses

The table and discussion below present research and development expenses for the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Direct research and development expenses by program:				
Key Clinical Programs				
RL-007 (Recognify)	$ 3,586	$ 2,492	$ 1,094	43.9%
VLS-01 (Viridia)	4,206	2,378	1,828	76.9%
DMX-1002 (DemeRx IB)	3,495	3,583	(88)	-2.5%
EMP-01 (EmpathBio)	4,365	1,534	2,831	184.6%
Other Clinical Programs				
PCN-101 (Perception)	14,206	6,862	7,344	107.0%
KUR-101 (Kures)	3,347	1,488	1,859	124.9%
RLS-01 (Revixia)	2,026	952	1,074	112.8%
Enabling Technologies and Drug Discovery Platforms	8,772	2,492	6,280	252.0%
Unallocated research and development expenses:				
Personnel expenses	28,716	25,244	3,472	13.8%
Professional and consulting services	1,006	451	555	123.1%
Other	588	479	109	22.7%
Total research and development expenses	$ 74,313	$ 47,956	$ 26,358	55.0%

Research and development expenses were $74.3 million for the year ended December 31, 2022, compared to $48.0 million for the year ended December 31, 2021. The increase of $26.3 million was primarily attributable to an increase of $22.2 million of direct costs at the platform companies as discussed below, a $3.5 million increase in personnel costs and a $0.6 million increase in professional and consulting fees.

Our Key Clinical Programs:

RL-007 (Recognify Life Sciences)

The $1.1 million increase in direct costs for the RL-007 program was primarily due to an increase of $0.8 million of clinical development costs and $0.3 million of manufacturing costs relating to the start of our Phase 2b proof-of-concept clinical trial for RL-007 in CIAS.

Viridia Life Sciences: VLS-01 (N,N-Dimethyltryptamine; DMT) for Treatment Resistant Depression (TRD)

The $1.8 million increase in direct costs for VLS-01 was primarily due to an increase of $1.7 million of clinical development costs and $0.2 million of preclinical development costs, partially offset by a decrease of $0.1 million of manufacturing costs relating to the initiation of our Phase 1 open-label, single ascending dose, two-part trial of VLS-01.

DemeRx IB: DMX-1002 (ibogaine) for OUD

The $0.1 million decrease in direct costs for the DMX-1002 program was primarily due to a decrease of $0.7 million of preclinical development costs, partially offset by an increase of $0.4 million of clinical development costs, $0.1 million of manufacturing costs, and $0.1 million of personnel related costs for the conduct of our ongoing Phase 1/2 trial to evaluate its safety, tolerability, pharmacokinetics, and efficacy in recreational drug users and healthy volunteers.

EmpathBio: EMP-01 (MDMA derivative) for PTSD

The $2.8 million increase in direct costs for EMP-01 was primarily due to an increase of $2.4 million preclinical activities as well as a $0.4 million increase of clinical development costs relating to the initiation our Phase 1 single ascending dose trial to assess the safety and tolerability of orally administered EMP-01.

Our Other Clinical Programs

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

The $7.3 million increase in direct costs for PCN-101 was primarily due to an increase of $4.8 million of clinical development costs, $1.1 million of preclinical development costs, $0.9 million of manufacturing costs for the conduct of our Phase 2a study of PCN-101, and $0.6 million of consulting and personnel related costs.

Kures: KUR-101(deuterated mitragynine) for OUD

The $1.9 million increase in direct costs for KUR-101 was primarily due to a $1.9 million increase of clinical development costs and a $0.2 million increase in preclinical development costs for the conduct of our Phase 1 study of KUR-101, partially offset by a decrease of personnel costs of $0.3 million, of which $0.1 million related to stock-based compensation.

Revixia Life Sciences: RLS-01 for TRD

The $1.1 million increase in direct costs for RLS-01 was primarily due to a $0.8 million increase of manufacturing costs and $0.3 million of preclinical development costs.

Enabling Technologies and Drug Discovery Platforms

The $6.3 million increase in our enabling technologies and drug discovery platforms primarily relates to increased direct costs of $3.4 million in our Invyxis program, $1.7 million in our TryptageniX program, $0.9 million in our EntheogeniX program and $0.4 million in our InnarisBio program. We also incurred immaterial costs in association with IntroSpect, Psyber, Psyprotix, and Neuronasal.

Acquisition of In-Process Research and Development Expense

	Year Ended December 31,			
	2022	2021	Change	% Change
	(in thousands, except percentages)			
Acquisition of in-process research and development expense by program:				
Kures	$ 357	$ —	$ 357	100.0%
Neuronasal	$ —	$ 7,962	$ (7,962)	-100.0%
TryptageniX	—	6,546	(6,546)	-100.0%
InnarisBio	—	972	(972)	-100.0%
Total acquisition of in-process research and development expense	$ 357	$ 15,480	$ (15,123)	-97.7%

Acquisition of in-process research and development expenses was $0.4 million for the year ended December 31, 2022, which relates to license costs incurred by Kures. Acquisition of in-process research and development expenses was $15.5 million for the year ended December 31, 2021, which was IPR&D acquired from InnarisBio in March 2021, Neuronasal in May 2021 and TryptageniX in December 2021. The acquired IPR&D was considered to have no future alternative use.

General and Administrative Expenses

General and administrative expenses were $70.4 million for the year ended December 31, 2022 compared to $92.7 million for the year ended December 31, 2021. The decrease of $22.3 million was largely attributable to a decrease of $18.0 million in non-cash stock compensation expense, $9.8 million decrease in value added tax expense and a $4.0 million decrease in professional consulting services. These decreases were partially offset by an increase of $7.3 million in personnel expenses and a $1.9 million increase in insurance expenses.

Interest Income

Interest income for the years ended December 31, 2022 and 2021 primarily consisted of interest earned on our cash balances and notes receivable during these periods. We had interest income for the years ended December 31, 2022 and 2021 of $0.5 million and $0.2 million, respectively.

Change in Fair Value of Contingent Consideration Liability—Related Parties

The milestone and royalty payments in relation to the acquisition of Perception Neuroscience, InnarisBio and TryptageniX were recorded at the acquisition date or at the exercise date related to the call option, and is subsequently remeasured to fair value quarterly. We recorded income of $1.5 million for the year ended December 31, 2022 compared to $0.2 million for the year ended December 31, 2021, an increase of $1.3 million. The change in the fair value of our contingent consideration liability was primarily attributable to updates to certain estimated assumptions in relation to Perception Neuroscience and TryptageniX.

Change in Warrant Liability

Change in warrant liability was an unrealized gain of $0.3 million and unrealized loss of $0.1 million for the years ended December 31, 2022 and 2021, respectively. Change in warrant liability for the year ended December 31, 2022 primarily consisted of an unrealized gain attributed to the deconsolidation of Neuronasal. The Company remeasured the Neuronasal warrant liability at fair value immediately prior to deconsolidation in November 2022. The fair value of the Neuronasal warrant liability was determined to be de minimis on November 9, 2022, resulting in a $0.3 million unrealized gain immediately prior to deconsolidation.

Unrealized Loss on Other Investments Held at Fair Value

In May 2021, we received IntelGenx common stock, warrants and additional unit warrants for a price of approximately $12.3 million. We determined that the initial aggregate fair value is equal to the transaction price and recorded the common shares at $3.0 million, the 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 our consolidated statements of operations. Subsequently, changes in fair value of the common stock, the warrants and additional unit warrants are recorded as a component of other income (expense), net in our consolidated statements of operations. During the year ended December 31, 2022, we recognized $0 of unrealized loss on other investments held at fair value. During the year ended December 31, 2021, we recognized $12.3 million of unrealized loss on other investments held at fair value.

We did not record an unrealized loss on other investments held at fair value for year ended December 31, 2022.

Loss on Conversion of Convertible Promissory Notes

Loss on conversion of convertible promissory notes for the year ended December 31, 2021 was $0.5 million. In June 2021, upon the funding of the Otsuka Agreement, the Perception convertible promissory notes were converted into Perception Series A preferred stock. The loss represents the difference between (i) carrying value including derivative liability of the Perception December 2020 Notes of $2.2 million and (ii) the fair value of Perception Series A preferred stock into which the notes converted of $2.7 million. There was no loss on conversion of convertible promissory notes recorded in the year ended December 31, 2022.

There was no loss on conversion of convertible promissory notes recorded in the year ended December 31, 2022.

Gain on Consolidation of a Variable Interest Entity

Gain on consolidation of a variable interest entity was $3.5 million for the year ended December 31, 2021. We purchased additional shares of Neuronasal in May 2021 and recognized a gain of $3.5 million. The gain was calculated as the sum of the consideration paid of $1.0 million, the fair value of the noncontrolling interest issued of $3.0 million, the carrying value of our investments in Neuronasal’s common stock and preferred stock prior to May 2021 of $0.8 million, less the fair value of identifiable net assets acquired of $8.3 million. The fair value of the IPR&D acquired of $8.0 million was charged to research and development expense as it had no alternative future use at the time of the acquisition.

There was no gain on consolidation of a variable interest entity recorded in the year ended December 31, 2022.

Gain on Deconsolidation of a Variable Interest Entity

Gain on deconsolidation of a variable interest entity was $1.5 million for the year ended December 31, 2022 as a result of the deconsolidation of Neuronasal. Upon the effective termination date in November 2022, we derecognized all of Neuronasal's assets and liabilities from our balance sheet, and recognized a gain of $1.5 million,

There was no gain on deconsolidation of a variable interest entity recorded in the year ended December 31, 2021.

Foreign Exchange Gain, Net

Foreign exchange gain, net was $6.9 million for the year ended December 31, 2022 compared to $8.5 million for the year ended December 31, 2021. The decrease of $1.6 million was primarily a result of 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, 2022 was $1.4 million, compared to $0.3 million for the year ended December 31, 2021. The increase of $1.1 million was primarily related to our impairment of a loan receivable recognized in relation to the impairment of the outstanding Neuronasal loans in connection with deconsolidation during the year ended December 31, 2022.

Benefit From (Provision For) Income Taxes

We incurred current income tax expense of $1.1 million and a deferred income tax expense of $5.1 million for the year ended December 31, 2022. 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, 2021. 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, 2022 primarily with regard to temporary timing difference arising in connection with share-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 share-based compensation that we consider-more-likely-than-not not to be realized.

Gain on Dilution of Equity Method Investment

In May 2021, COMPASS completed an additional round of equity financing through the offering of 4,000,000 American Depository Shares. We participated in this financing round but did not purchase enough shares to maintain an ownership percentage equal to what we owned prior to the financing. As the purchase of shares resulted in a decrease in our equity ownership percentage in COMPASS, we recorded a gain on dilution of $16.9 million for the year ended December 31, 2021.

Losses from Investments in Equity Method Investees

Losses from investment in equity method investees for the years ended December 31, 2022 and 2021 were $16.0 million and $58.6 million, respectively. Loss from investment in equity method investees represents our share of equity method investee losses on the basis of our equity ownership percentages or based on our proportionate share of the respective class of securities in our other investments in the event that the carrying amount of our equity method investments was zero.

Liquidity and Capital Resources

Overview

For the years ended December 31, 2022 and 2021, we had net losses attributable to ATAI Life Sciences N.V. shareholders of $152.4 million and $167.8 million, respectively. As of December 31, 2022 and 2021, our accumulated deficit was $510.2 million and $357.8 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 and short-term securities, 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 of our 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, 2022, we had cash and cash equivalents of $190.6 million and short-term securities of $82.5 million.

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. In 2021, several 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 €5.8 million ($6.9 million) in order to convert their respective 2018 Convertible Notes into ATAI Life Sciences AG common shares. In May and July 2022, certain investors elected to convert some of their 2018 Convertible Notes into shares of ATAI Life Sciences N.V. The investors each paid €17.00 per share for an aggregate amount of €4.6 million ($4.6 million) in

order to convert their respective 2018 Convertible Notes into ATAI Life Sciences AG common shares. 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 investors who elected to convert their respective 2018 Convertible Notes in 2021 and in May and July 2022 were then exchanged for shares of ATAI Life Sciences N.V. on a one to one basis 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. The remaining 2018 Convertible Notes balance as of December 31, 2022, 2022 was $0.4 million.

Investments

While a significant potential source of liquidity resides in our investment in COMPASS's American Depositary shares, we do not expect that our investment in COMPASS will be a material source of liquidity in the near term. Based on quoted market prices, the market value of our ownership in COMPASS was $76.8 million as of December 31, 2022. As of December 31, 2022, the carrying value of our investment in COMPASS was $0 million under the equity method. As of December 31, 2022, our voting interest in COMPASS was 22.4%.

Hercules Term Loan

On August 9, 2022, we entered into the Loan Agreement with Hercules See " "—Liquidity and Capital Resources—Indebtedness—Hercules Term Loan" for additional information.

Liquidity Risks

As of December 31, 2022, we had cash and cash equivalents of $190.6 million and short-term securities of $82.5 million. We believe that our cash and cash equivalents and short-term securities will be sufficient to fund our projected operating expenses and capital expenditures through at least the next 12 months from the date of this Annual Report.

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 of our portfolio 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, 2022 and 2021:

	December 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (104,467)	$ (63,246)
Net cash used in investing activities	(86,848)	(81,276)
Net cash provided by financing activities	20,785	409,862
Effect of foreign exchange rate changes on cash	(1,123)	(320)
Net increase (decrease) in cash	$ (171,653)	$ 265,020

Net Cash Used in Operating Activities

Net cash used in operating activities was $104.5 million for the year ended December 31, 2022, which consisted of a net loss of $157.4 million, adjusted by non-cash charges of $56.3 million and net cash outflows from the change in operating assets and liabilities of $3.3 million. The non-cash 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 operating activities was $63.2 million for the year ended December 31, 2021, which consisted of a net loss of $174.2 million, adjusted by non-cash charges of $118.6 million and net cash outflows from the change in operating assets and liabilities of $7.6 million. The non-cash charges primarily consisted of $63.4 million of stock-based compensation, $15.5 million of IPR&D considered to have no future alternative use, $58.6 million of losses from our equity method investments and $12.3 million of unrealized loss on other investments held at fair value, partially offset by $11.4 million of unrealized foreign exchange gains, $16.9 million of gain on investment dilution and a $3.5 million gain on consolidation of variable interest entities. The net cash outflows from the change in operating assets and liabilities were primarily due to a $5.0 million increase in prepaid expenses, a $4.4 million increase in other receivables, a $5.1 million increase in our deferred tax asset, partially offset by a net $2.3 million increase in accounts payable, partially offset by a $5.7 million increase in accrued liabilities.

Net Cash Used in Investing Activities

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 used in investing activities was $81.3 million for the year ended December 31, 2021, primarily driven by $52.9 million additional investments into equity-method investees, additional investments of $11.3 million in our other investments, additional investments of $12.3 million in our other investments held at fair value, $2.6 million of loans remitted to related parties, $1.0 million of cash paid for asset acquisitions, $1.0 million of capitalized internal-use software development costs and $0.2 million of purchases of property and equipment.

Net Cash Provided by Financing Activities

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.

Net cash provided by financing activities was $409.9 million for the year ended December 31, 2021, primarily due to $409.9 million of proceeds from the issuance of our common shares, $6.9 million of proceeds from conversion of convertible notes to common shares, $2.4 million of proceeds from our sale of Innoplexus AG investments treated as a secured financing, $1.6 million of proceeds from the issuance of convertible promissory notes and $0.9 million of proceeds from stock option exercises. The net cash influx was offset by $12.4 million paid for common share issuance costs.

Indebtedness

Convertible Notes

In November 2018, we issued an aggregate principal amount of $0.2 million of the 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 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. Conversion rights may be exercised by a noteholder at any time prior to maturity, except during certain periods subsequent to the consummation of the IPO. In 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 the aggregate amount of €5.8 million ($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, additional 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. Concurrent 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 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. As of December 31, 2022 an aggregate principal amount of $0.4 million remained outstanding under the 2018 Convertible Notes.

In March 2020, we received proceeds of $0.6 million from the issuance of Perception Notes, as defined below, to third party investors. In December 2020, January 2021, and May 2021 we received $0.4 million, $0.8 million, and $0.8 million respectively, in proceeds from the issuance of additional Perception Notes. The Perception Notes are convertible upon mandatory conversion events into shares of Perception. The Perception Notes converted in June 2021 in connection with the receipt of proceeds of $20.0 million pursuant to the Otsuka Agreement.

Investment in Convertible Promissory Notes—Related Party

On March 16, 2020, Perception entered into a convertible promissory note agreement with us and certain other unrelated investors (the "First Perception Note Purchase Agreement"), pursuant to which Perception issued $3.9 million in principal amount of convertible notes in aggregate (the "First Perception Notes"). Under the First Perception Note Purchase Agreement, Perception issued the First Perception Notes in an aggregate principal amount of $3.3 million to us and $0.6 million to other investors, including related parties. The First Perception Notes bear interest at an annual rate of 5% and were due and payable on June 30, 2022 unless earlier converted. In December 2020, Perception entered into an additional convertible promissory note agreement with us and certain other unrelated investors (the "Second Perception Note Purchase Agreement"), pursuant to which Perception issued additional convertible notes (the "Second Perception Notes" and together with the First Perception Notes, the "Perception Notes") to us, certain related parties and third party investors in an aggregate principal amount of $7.0 million, of which $5.8 million was issued to us and $1.2 million was issued to other investors, including related parties. In January 2021, pursuant to the Second Perception Note Purchase Agreement, Perception issued the Second Perception Notes in an aggregate principal amount of $0.8 million to other investors, including related parties, as part of its first tranche funding. In May 2021, Perception issued additional Second Perception Notes to us, certain related parties and third party investors in an aggregate principal amount of $5.0 million, of which $4.2 million was issued to us and $0.8 million was issued to other investors, including related parties, as part of its second tranche funding. The Second Perception Notes bear interest at an annual rate of 5% and were due and payable on February 28, 2022, unless earlier converted. Perception may not prepay in whole or in part without our consent.

In June 2021, Perception received proceeds of $20.0 million pursuant to the Otsuka Agreement. Upon receipt of the proceeds, the Perception Notes automatically converted into 6,456,595 shares of Series A preferred stock of Perception pursuant to their original terms.

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 (as amended by the certain First Amendment to Loan and Security Agreement dated as of March 13, 2023, the "Loan Agreement") 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 may become parties to the Loan Agreement 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 (the "2022 Term Loan Facility"), available as follows: (i) a term loan advance in the amount of $15.0 million on the Closing Date (the "Tranche 1A Advance"); (ii) at any time after the Closing Date but on or prior to May 1, 2023 (the "Tranche 1B Expiration Date"), term loan advances in an aggregate principal amount of up to $20.0 million (the "Tranche 1B Advances"); (iii) at any time beginning upon the earlier of (A) the Tranche 1B Expiration Date and (B) the date on which all amounts available to be drawn under the Tranche 1B Advances have been drawn and on or prior to December 15, 2023 (the "Tranche 1C Expiration Date"), term loan advances in an aggregate principal amount of up to $25.0 million (the "Tranche 1C Advances" and together with the Tranche 1A Advance and the Tranche 1B Advances, the "Tranche 1 Advances"); (iv) subject to us achieving certain performance milestones and, beginning upon the earlier of (A) the date on which all amounts available to be drawn under the Tranche 1C Advances have been drawn and (B) the Tranche 1C Expiration Date, on or prior to June 30, 2024, term loan advances in an aggregate principal amount of $15.0 million (the "Tranche 2 Advances"); and (v) subject to approval by the Lenders' respective investment committees in its discretion, on or prior to March 31, 2025, term loan advances in an aggregate principal amount of up to $100.0 million (the "Tranche 3 Advances"). With the exception of the first $15.0 million tranche which was drawn on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at our election, subject to applicable conditions to draw. We have agreed to use the proceeds of the 2022 Term Loan Facility for working capital and general business purposes.

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 June 30, 2024, and satisfy 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. 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, ATAI AG 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 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 our market capitalization is at least $600.0 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, 2022, 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.

Contractual Obligations and Commitments

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 3 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, 2022 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, 2022, 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 license as research & 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 was also expensed as research & development expense during the year ended December 31, 2022. During the year ended December 31, 2022 we recognized $0.4 million of IPR&D expense in connection with the SPA and the License Agreement.

During the year ended December 31, 2022, we made no material payments in connection with the Columbia agreement.

Accelerate License Agreement

On April 27, 2021, Psyber entered into a license arrangement (the "Accelerate License Agreement") with Accelerate Technologies Pte. Ltd. ("Accelerate"), whereby Accelerate grants Psyber non-exclusive rights to license and use the technology to commercialize of Psyber's BCI-enabled companion digital therapeutics in United States of America, Singapore, Member Countries of the European Union, Canada, Australia and New Zealand as a potential treatment for mental health and behavior change, such as substance use disorders including opioid use disorder, mood and anxiety disorders including post-traumatic stress disorder, and treatment-resistant depression. Psyber will pay Accelerate an upfront payment of $0.1 million, up to $0.3 million upon the achievement of certain clinical and sale milestones, and low to mid-single digit royalty payments based on net sales.

As of December 31 2022, we had made no material payments pursuant to the Accelerate License 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 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 expensed 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, 2022, we recorded $2.8 million as research and development expense. We did not record a material amount of research & development expense for the year ended December 31, 2021. During the years ended December 31, 2022 and 2021, Invyxis made no other service fee payments to Dalriada.

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, "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, 2022 and 2021, 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.

Share-Based Compensation

We recognize compensation costs related to share-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 share-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 share-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 share-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 share-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, "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 JOBS Act. We intend to rely on certain of the exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). We have elected to use the 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 (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

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, 2022, we had cash and cash equivalents of $190.6 million and short-term securities of $82.5 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, 2022, we had $0.4 million in convertible promissory notes – related parties, net, 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, 2022, the carrying amount of our short and long-term notes receivables was an aggregate amount of $7.2 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 condensed 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 condensed 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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, redeemable noncontrolling interests and stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 24, 2023

We have served as the Company's auditor since 2020.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 190,613	$ 362,266
Securities carried at fair value	82,496	—
Prepaid expenses and other current assets	14,036	11,903
Short term notes receivable	—	913
Total current assets	287,145	375,082
Property and equipment, net	928	149
Equity method investments	—	16,131
Other investments	6,755	11,628
Long term notes receivable - related parties	7,262	3,835
Other assets	3,351	7,341
Total assets	$ 305,441	$ 414,166
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	2,399	6,004
Accrued liabilities	17,306	14,829
Current portion of contingent consideration liability - related parties	—	51
Other current liabilities	192	51
Total current liabilities	19,897	20,935
Non-current portion of contingent consideration liability - related parties	953	2,432
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	415	743
Long-term debt, net	14,702	—
Other liabilities	3,708	4,097
Total liabilities	$ 39,675	$ 28,207
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, €0.10 par value ($0.12 par value at December 31, 2022 and December 31, 2021, respectively); 750,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 165,935,914 and 160,677,001 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	18,562	18,002
Additional paid-in capital	774,092	725,045
Share subscription receivable	(24)	—
Accumulated other comprehensive loss	(21,702)	(8,336)
Accumulated deficit	(510,188)	(357,803)
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	260,740	376,908
Noncontrolling interests	5,026	9,051
Total stockholders' equity	265,766	385,959
Total liabilities and stockholders' equity	$ 305,441	$ 414,166

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)

	Years Ended December 31,	
	2022	2021
License revenue	$ 233	$ 20,376
Operating expenses:		
Research and development	74,313	47,956
Acquisition of in-process research and development	357	15,480
General and administrative	70,350	92,745
Total operating expenses	145,020	156,181
Loss from operations	(144,787)	(135,805)
Other income (expense), net:		
Interest income	548	205
Change in fair value of contingent consideration liability - related parties	1,475	173
Change in fair value of derivative liability	—	41
Change in fair value of warrant liability	336	(87)
Change in fair value of securities carried at fair value	272	—
Unrealized loss on other investments held at fair value	—	(12,346)
Loss on conversion of convertible promissory notes	—	(513)
Gain on consolidation of a variable interest entity	—	3,543
Gain on deconsolidation of a variable interest entity	1,484	—
Foreign exchange gain, net	6,902	8,481
Other expense, net	(1,412)	(293)
Total other income (expense), net	9,605	(796)
Loss before income taxes	(135,182)	(136,601)
Benefit from (provision for) income taxes	(6,229)	3,989
Gain on dilution of equity method investment	—	16,923
Losses from investments in equity method investees, net of tax	(16,006)	(58,555)
Net loss	(157,417)	(174,244)
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(5,032)	(6,436)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (152,385)	$ (167,808)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.98)	$ (1.21)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	155,719,585	138,265,859

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2022	**2021**
Net loss	$ (157,417)	$ (174,244)
Other comprehensive income (loss):		
Foreign currency translation adjustments, net of tax	(13,366)	(14,155)
Comprehensive loss:	$ (170,783)	$ (188,399)
Comprehensive loss attributable to redeemable noncontrolling interests and noncontrolling interests	(5,032)	(6,436)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests	50	(24)
Comprehensive loss attributable to redeemable noncontrolling interests and noncontrolling interests	(4,982)	(6,460)
Comprehensive loss attributable to ATAI Life Sciences N.V. stockholders	$ (165,801)	$ (181,939)

See accompanying notes to the consolidated financial statements.

ATAI LIFE SCIENCES N.V.
CONSOLIDATED STATEMENTS OF REDEEMABLE NONCONTROLLING INTERESTS AND STOCKHOLDERS' EQUITY
(Amounts in thousands, except share and per share amounts)

	Redeemable Noncontrolling Interests	Common Stock Shares	Common Stock Amount	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
Balances at December 31, 2020	$ —	114,735,712	$ 13,372	$ 261,626	$ —	$ 5,819	$ (189,995)	$ 90,822	$ 4,546	$ 95,368
Issuance of common shares for Series C and Series D financing, net of issuance costs of $4.9 million	—	15,552,688	1,881	162,497	(140,868)	—	—	23,510	—	23,510
Issuance of common shares for IPO, net of issuance costs of $9.0 million	—	17,250,000	2,046	229,535	—	—	—	231,581	—	231,581
Issuance of common shares under the Hurdle Share Option Plan (see Note 12)	—	7,281,376	—	—	—	—	—	—	—	—
Settlement of issuance of common shares, net of issuance costs of $4.9 million	—	—	—	—	140,868	—	—	140,868	—	140,868
Conversion of convertible notes to common stock	—	5,478,176	646	6,613	—	—	—	7,259	—	7,259
Issuance of noncontrolling interest	2,555	—	—	—	—	—	—	—	8,411	8,411
Issuance of shares upon exercise of stock options	—	379,049	45	890	—	—	—	935	—	935
Exercise of Hurdle Share Option Plan award (see Note 12)	—	—	12	522	—	—	—	534	—	534
Stock-based compensation expense	—	—	—	63,362	—	—	—	63,362	—	63,362
Foreign currency translation adjustment, net of tax	—	—	—	—	—	(14,155)	—	(14,155)	(24)	(14,179)
Net income (loss)	(2,555)	—	—	—	—	—	(167,808)	(167,808)	(3,882)	(171,690)
Balances at December 31, 2021	$ —	160,677,001	$ 18,002	$ 725,045	$ —	$ (8,336)	$ (357,803)	$ 376,908	$ 9,051	$ 385,959
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
Issuance of subsidiary preferred shares	—	—	—	—	—	—	—	—	600	600
Issuance of subsidiary common shares	—	—	—	—	—	—	—	—	357	357
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

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (157,417)	$ (174,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	168	47
Amortization of debt discount	131	195
Change in fair value of contingent consideration liability—related parties	(1,475)	(173)
Change in fair value of securities carried at fair value	(272)	—
Provision for deferred income taxes	5,074	—
Change in fair value of derivative liability	—	(41)
Impairment of loan receivable	852	—
Change in fair value of warrant liability	(336)	87
Unrealized loss on other investments held at fair value	—	12,346
Gain on dilution of equity method investment	—	(16,923)
Loss on conversion of convertible notes	—	513
Gain on consolidation of a variable interest entity	—	(3,543)
Gain on deconsolidation of a variable interest entity	(1,484)	—
Losses from investments in equity method investees	16,006	58,555
In-process research and development expense	357	15,480
Stock-based compensation expense	42,375	63,362
Unrealized foreign exchange gains	(4,950)	(11,346)
Other	(161)	43
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,522)	(9,699)
Other assets	—	(5,973)
Accounts payable	(3,034)	2,300
Accrued liabilities	1,221	5,756
Deferred revenue	—	12
Net cash used in operating activities	(104,467)	(63,246)
Cash flows from investing activities		
Purchases of property and equipment	(773)	(173)
Capitalized internal-use software development costs	(251)	(955)
Cash paid for securities carried at fair value	(309,058)	—
Proceeds from sale and maturities of securities carried at fair value	226,834	—
Cash acquired in asset acquisitions, net	—	47
Cash paid for asset acquisitions, net	—	(1,000)
Cash paid for equity method investments	—	(52,937)
Cash paid for other investments	(600)	(23,658)
Loans to related parties	(3,000)	(2,600)
Net cash used in investing activities	(86,848)	(81,276)
Cash flows from financing activities		
Proceeds from issuance of common stock	—	409,884
Cash paid for common stock issuance costs	—	(12,350)
Proceeds from issuance of share option awards	—	534
Proceeds from secured borrowing liability	—	2,417
Proceeds from issuance of shares upon exercise of stock options	2,294	935
Proceeds from issuance of subsidiary preferred shares	600	—
Proceeds from conversion of convertible notes to common stock	4,636	6,854
Proceeds from debt financings	15,000	—
Financing costs paid	(1,745)	—
Proceeds from issuance of convertible promissory notes	—	1,588
Net cash provided by financing activities	20,785	409,862
Effect of foreign exchange rate changes on cash	(1,123)	(320)
Net increase (decrease) in cash and cash equivalents	(171,653)	265,020
Cash and cash equivalents – beginning of the period	362,266	97,246
Cash and cash equivalents – end of the period	$ 190,613	$ 362,266
Supplemental disclosures:		
Cash paid for interest	$ 508	$ —
Cash paid for taxes	$ 652	$ —
Supplemental disclosures of non cash investing and financing information:		
Right of use asset obtained in exchange for operating lease liabilities	$ 487	$ —
Issuance of subsidiary shares to non-controlling interests in connection with Columbia stock purchase agreement	$ 357	$ —
Share subscription receivable	$ 24	$ —
Fair value of noncontrolling interests issued in connection with consolidation of a VIE	$ —	$ 392
Fair value of redeemable noncontrolling interests issued in connection with consolidation of a VIE	$ —	$ 2,555
Fair value of noncontrolling interests issued in connection with asset acquisitions	$ —	$ 4,761
Issuance of derivative instrument related to convertible promissory notes	$ —	$ 646
Exercise of Hurdle Share Option Plan award	$ —	$ 527
Issuance of subsidiary shares in connection with the conversion of convertible notes	$ —	$ 3,258

See accompanying notes to the consolidated financial statements.

1. Organization and Description of Business

ATAI Life Sciences N.V. ("atai") 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. atai is dedicated to acquiring, incubating and efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders.

Since inception, atai has either created wholly owned subsidiaries or has made investments in certain controlled entities, including variable interest entities ("VIEs") for which atai is the primary beneficiary under the VIE model (collectively, the "Company"). atai is headquartered in Berlin, Germany.

The Company has determined that it has one operating and reporting segment.

Corporate Reorganization and Initial Public Offering

atai was incorporated pursuant to the laws of the Netherlands as a Dutch private company with limited liability on September 10, 2020 for the purposes of becoming a holding company for ATAI Life Sciences AG and consummating the corporate reorganization described below. atai did not conduct any operations prior to the corporate reorganization other than activities incidental to its formation. ATAI Life Sciences AG was formed as a separate company on February 7, 2018.

In contemplation of the consummation of atai's initial public offering ("IPO") of common shares, atai undertook a corporate reorganization (the "Corporate Reorganization"). The Corporate Reorganization consisted of several steps as described below:

- **Exchange of ATAI Life Sciences AG Securities for ATAI Life Sciences B.V. Common Shares and Share Split**: In April 2021, the existing shareholders of ATAI Life Sciences AG each became a party to a separate notarial deed of issue under Dutch law and (i) subscribed for new common shares in ATAI Life Sciences B.V. and (ii) transferred their respective shares in ATAI Life Sciences AG, on a 1 to 10 basis (the "Exchange Ratio"), to ATAI Life Sciences B.V. as a contribution in kind on the common shares in ATAI Life Sciences B.V. As a result of the issuance of common shares in ATAI Life Sciences B.V. to the shareholders of ATAI Life Sciences AG and the contribution and transfer of their respective shares in ATAI Life Sciences AG to ATAI Life Sciences B.V., ATAI Life Sciences AG became a wholly owned subsidiary of ATAI Life Sciences B.V. No shareholder rights or preferences changed as a result of the share for share exchange. In connection with such exchange, the common share in ATAI Life Sciences B.V. held by Apeiron was cancelled. On June 7, 2021, shares of ATAI Life Sciences B.V. were split applying a ratio of 1.6 to one, and the nominal value of the shares was reduced to €0.10, pursuant to a shareholders' resolution and amendment to the articles of association.

- **Conversion of ATAI Life Sciences B.V. into ATAI Life Sciences N.V.**: Immediately preceding the Company's IPO, the legal form of ATAI Life Sciences B.V. was converted from a Dutch private company with limited liability to a Dutch public company, and the articles of association of ATAI Life Sciences N.V., became effective. Following the Corporate Reorganization, ATAI Life Sciences N.V. became the holding company of ATAI Life Sciences AG.

The Corporate Reorganization, as described above, is considered a continuation of ATAI Life Sciences AG resulting in no change in the carrying values of assets or liabilities. As a result, the financial statements for periods prior to the Corporate Reorganization are the financial statements of ATAI Life Sciences AG as the predecessor to atai for accounting and reporting purposes. All share, per-share and related information presented in these consolidated financial statements and corresponding disclosure notes have been retrospectively adjusted, where applicable, to reflect the impact of the share exchange and share split resulting from the Corporate Reorganization. In connection with the Corporate Reorganization, outstanding share awards and option grants of ATAI Life Sciences AG were exchanged for share awards and option grants of ATAI Life Sciences B.V. with identical restrictions.

On June 22, 2021, atai closed the IPO of its common shares on the Nasdaq Stock Market ("Nasdaq"). As part of the IPO, the Company issued and sold 17,250,000 shares of its common shares, 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 approximately $231.6 million from the IPO, after deducting underwriters' discounts and commissions of $18.1 million and offering costs of $9.0 million.

Impact of COVID-19 Pandemic

The COVID-19 pandemic has continued to present global public health and economic challenges during the year ended December 31, 2022. The Company has not experienced material financial impacts on its business and operations. The Company continues to monitor the impact of the COVID-19 pandemic on its employees and business and has undertaken business continuity measures to mitigate potential disruption to its operations.

The future impact of COVID-19 on the Company's business and operations, including its research and development programs and related clinical trials, will largely depend on future developments, which are highly uncertain, such as the duration of the pandemic, the spread of the disease and variants thereof, the availability and effectiveness of vaccines and related roll-out efforts, breakthrough infections among the vaccinated, vaccine hesitancy, the implementation of vaccine mandates, travel restrictions, social distancing and related government actions around the world, business closures or business disruptions and the ultimate impact of COVID-19 on financial markets and the global economy.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2022, the Company had cash and cash equivalents of $190.6 million, short-term securities of $82.5 million and its accumulated deficit was $510.2 million. The Company has historically financed its operations through the sale of equity securities, debt financings, sale of convertible notes 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 currently expects that its existing cash and cash equivalents and short-term securities as of December 31, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date the consolidated financial statements are issued.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of our financial position, our results of operations and comprehensive loss, and our cash flows for the periods presented. The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiaries. 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"). All intercompany transactions and accounts have been eliminated in consolidation.

For consolidated entities where the Company owns or is exposed to less than 100% of the economics, the Company allocates net losses between the controlling and the noncontrolling interests in its consolidated statements of operations after considering the liquidation preference and the equity ownership percentages. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of subsidiaries.

The results of operations for the years ended December 31, 2022 and 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period.

Use of Estimates

The preparation of consolidated 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 the Company's investment in Intelgenx Technologies Corp. ("IntelGenx"), securities carried at fair value, contingent consideration liability—related parties, in-process research and development ("IPRD") assets, derivative liability associated with the Perception convertible promissory notes, redeemable noncontrolling interests and noncontrolling interests recognized in acquisitions, the valuations of common shares prior to IPO and share-based awards, and accruals for research and development costs.

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.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of December 31, 2022 and through the issuance of these consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses. The Company has not experienced any significant financial impacts due to COVID-19.

Risks and Uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry. The Company believes that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, product candidates; performance of third-party clinical research organizations and manufacturers upon which the Company relies; protection of the Company's intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; and the Company's ability to attract and retain employees.

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, United Kingdom, Germany and Australia. 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 has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

Segments

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.

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, 2022 and December 31, 2021, 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 following table sets forth the fair value of atai's available-for-sale securities portfolio at the dates indicated:

	Fair Value	
	December 31, 2022	**December 31, 2021**
Money Market Funds	$ 72,334	$ —
Commercial Paper	5,958	—
Corporate Notes/Bonds	17,719	—
U.S. Government Agencies	58,819	—
	$ 154,830	$ —

In January 2022, the Company invested in a certain 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 (see Note 7). 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 securities 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 two years.

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. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter. The following table provides the range of estimated useful lives used for each asset type:

Furniture and fixtures	7 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

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 (See Note 4).

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 (See Note 4).

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, 2022 and 2021, 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 atai is the primary beneficiary, the transactions are accounted for under ASC 810, *Consolidation*, and no goodwill is recognized. Rather, the Company recognizes the identifiable assets acquired (excluding goodwill), the liabilities assumed, and any noncontrolling interests as though the VIE was a business and subject to the guidance on recognition and measurement in a business combination under ASC 805, and recognizes a gain or loss for the difference between (a) the sum of the fair values of consideration paid (including any contingent consideration) and noncontrolling interests, (b) the fair value of the VIE's identifiable assets and liabilities, and (c) the reported amounts of any previously held interests. Acquisition-related expenses incurred by the Company in asset acquisitions that involve the initial consolidation of a VIE that is not a business, are not included as a component of consideration transferred, but are accounted for as an expense in the period in which the costs are incurred. In an asset acquisition, including the initial consolidation of a VIE that is not a business, acquired IPR&D with no alternative future use is charged to research and development expense at the acquisition date.

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 non-consolidated 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 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 losses from investments in equity method investees on the consolidated statement of operations. The Company did not identify factors that would indicate that a potential other-than-temporary impairment of the carrying values of its equity method investments had occurred during the years ended December 31, 2022 and 2021.

Fair Value Option

As permitted under ASC 825, *Financial Instruments*, or ASC 825, the Company has elected the fair value option to account for its investment in common shares of IntelGenx, which otherwise would be subject to ASC 323. In accordance with ASC 825, the Company records this investment at fair value under Other investments held at fair value in the Company's consolidated balance sheets and changes in fair value are recognized as a component of other income (expense), net in the consolidated statements of operations. The carrying value of the investment remained at zero as of December 31, 2022 and December 31, 2021, respectively.

The Company has also elected the fair value option for its investment securities portfolio.

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 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.

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 impairment losses recognized. Generally, a loan is considered to be impaired when it is probable that the Company will not be able to collect any remaining amounts due in accordance with contractual terms of the loans and the amount of the loss can be reasonably estimated. As of December 31, 2022, there is no impairment loss recognized associated with the notes receivable that are carried at cost. 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—Related Parties

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 recorded as a liability on the consolidated balance sheet. The contingent consideration is re-valued on a quarterly basis using a discounted cash-flow valuation technique until fulfillment of the contingency. Changes in the fair value of the contingent consideration are recognized as a component of other income (expense), net in the consolidated statements of operations.

Convertible Promissory Notes

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all of its financial instruments, including convertible promissory notes, to determine if such instruments contain features that meet the definition of embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the consolidated statements of operations at each reporting period. Bifurcated embedded derivatives are classified with the related host contract in the Company's consolidated balance sheets.

On March 16, 2020, Perception entered into a convertible promissory note agreement with the Company and other investors, including related parties, which provided for the issuance of convertible notes of $3.3 million to the Company and $0.6 million to other investors. On December 1, 2020, Perception entered into an additional convertible promissory note agreement with the Company and other investors, including related parties, which provided for the issuance of convertible notes of up to $12.0 million to the Company in aggregate of which (i) $6.2 million and $0.8 million were issued in December 2020 and January 2021, respectively, under the First Tranche Funding and (ii) $5.0 million was issued under the Second Tranche Funding in May 2021 (See Note 10). The Perception convertible promissory notes issued to the Company represent intercompany debt and are eliminated upon consolidation.

In addition, the Perception convertible promissory notes contain certain embedded features, which are redemption features and meet the definition of derivative instruments. The Company classifies these instruments as a liability on its consolidated balance sheets as the redemption features involve substantial discounts, provide for the accelerated repayment of the notes upon the occurrence of specified events, and are not clearly and closely related to its host instrument. The derivative liability was initially recorded at fair value upon issuance of the convertible promissory notes and is subsequently remeasured to fair value at each reporting date. Both the Perception convertible promissory notes and the derivative liability were classified as long-term and presented as convertible promissory notes and derivative liability in the Company's consolidated balance sheets.

Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net in the consolidated statements of operations. Changes in the fair value of the derivative liability were recognized until the convertible promissory notes converted in June 2021. As such, the derivative liability balance is $0 as of December 31, 2022 and December 31, 2021, respectively.

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 share-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 share-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. Refer to Note 4 for further information.

Redeemable Noncontrolling Interests

Noncontrolling interests related to certain consolidated VIEs are subject to redemptions by third-party investors. As these interests are redeemable upon the occurrence of events that are not solely within the control of the Company, amounts relating to third-party interests in such consolidated entities are classified in the temporary equity as redeemable noncontrolling interest within the consolidated balance sheets. The redeemable noncontrolling interests related to its consolidated VIEs are initially recorded at fair value. Net losses in consolidated VIEs are attributed to redeemable noncontrolling interests considering their liquidation preferences for the different classes of equity held by the shareholders in the VIE and their respective interests in the net assets of the consolidated VIE.

The amount of net loss attributable to redeemable noncontrolling interests are included in the consolidated net loss on the face of the consolidated statements of operations. Refer to Note 4 for further information.

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.

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 Company's contingent consideration liability—related parties, derivative liability associated with the Perception convertible promissory notes, IntelGenx Initial Warrants and Additional Unit Warrants, and warrant liability with Neuronasal, Inc. are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (See Note 7). The IntelGenx common stock is carried at fair value, determined according to Level 2 inputs in the fair value hierarchy above. The carrying amount reflected in the accompanying consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

The carrying amounts of the Company's remaining outstanding convertible promissory notes—related parties issued in 2018 and 2020 (collectively, the "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, 2022, the carrying amount and fair value amount of the 2018 Convertible Notes was $0.4 million and $13.1 million, respectively. As of December 31, 2021, the carrying amount and fair value amount of the 2018 Convertible Notes was $0.8 million and $69.7 million, respectively. Several noteholders of the 2018 Convertible Notes elected to convert their promissory notes into shares of the Company's common stock during the years ended December 31, 2022 and 2021, respectively. See Note 10 for additional discussion.

The carrying amounts of the Perception convertible promissory notes issued during 2020, do not approximate fair value because carrying amounts are net of unamortized debt discounts and bifurcated derivative liabilities. The fair value of the Perception convertible promissory notes was determined based on the changes in expectation and increase in probability of occurrence of certain conversion events, including a qualified equity financing and a licensing transaction, that would have beneficial conversion terms for the note holders. In June 2021, the Perception convertible promissory notes converted into shares of Series A preferred stock of Perception pursuant to their original terms. As of December 31, 2022 and December 31, 2021 there were no Perception convertible promissory notes outstanding. See Note 10 for additional discussion.

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.

As described in "Recently Adopted Accounting Pronouncements" below, the Company early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies. The Company expects to use the extended transition period for any other new or revised accounting standards during the period in which it remains an emerging growth company.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of Topic 842 requires lessees to recognize on the consolidated balance sheets a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases with lease terms greater than twelve months. The lease liability is measured at the present value of the unpaid lease payments and the right-of-use asset is derived from the calculation of the lease liability. Topic 842 also requires lessees to disclose key information about leasing arrangements. For public entities, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-02 is effective for the Company beginning after December 15, 2021.

The Company adopted the new standard on January 1, 2022 using the modified transition approach as of the effective date.

The new standard provides 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.

The most significant impact of the adoption of Topic 842 on the Company's consolidated financial statements was 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 Company did not have a deferred rent liability recorded in connection with its existing facility operating lease. There was no material impact to the Company's consolidated balance sheet, statement of operations, and no cumulative-effect adjustment to accumulated deficit. The Company recorded an immaterial amount of general and administrative expense in its consolidated statement of operations related to lease expense, including short-term lease expense during the year ended December 31, 2022.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments — Credit Losses. This update requires immediate recognition of management's estimates of current expected credit losses. Under the prior model, losses were recognized only as they were incurred. The new model is applicable to most financial assets and certain other instruments that are not measured at fair value through net income. In November 2019, the FASB issued ASU 2019-10, which delays adoption for "smaller reporting companies" as defined under the rules promulgated under the Exchange Act.

The allowance for credit losses is a valuation account which is presented separately on the consolidated balance sheet by deducting it from the assets amortized cost. Furthermore, the allowance for credit losses is adjusted each period to reflect the movement in expected credit losses.

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. The Company will adopt ASU 2016-13 effective January 1, 2023 with the cumulative effect of adoption recorded as an adjustment to accumulated deficit. We estimate the adoption impact to be in the range of $0.5 million to $0.8 million.

3. Acquisitions and Dispositions

2021 Acquisitions

PsyProtix, Inc.

In February 2021, the Company jointly formed PsyProtix with Chymia, LLC ("Chymia"). PsyProtix was created for the purpose of exploring and developing a metabolomics-based precision psychiatry approach, initially targeting the stratification and treatment of Treatment Resistant Depression ("TRD") patients. In February 2021, pursuant to a Series A Preferred Stock Purchase Agreement (the "PsyProtix Purchase Agreement"), the Company acquired shares of PsyProtix's Series A preferred stock in exchange for an initial payment of $0.1 million in cash. In addition, pursuant to the PsyProtix Purchase Agreement, the Company agreed to make aggregate payments to PsyProtix of up to $4.9 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding to PsyProtix. The PsyProtix Purchase Agreement resulted in the Company holding a 75.0% voting interest and Chymia holding a 25.0% voting interest in PsyProtix. In connection with the Company's agreement for additional funding, PsyProtix issued the corresponding Series A preferred shares to the Company provided that the shares are held in an escrow account (the "PsyProtix Escrow Shares"). The PsyProtix Escrow Shares will be released, from time to time, to the Company upon PsyProtix achieving certain milestones as defined in the PsyProtix Purchase Agreement with cash payments to be made by the Company. In addition, the Company has the right, but not the obligation, to make payment for the certain PsyProtix Escrow Shares at any time, regardless of the achievement of any milestones. The PsyProtix Escrow Shares have voting and all other rights until an event of default occurs where the Company fails to make a payment within 10 days following the written notice of the achievement of the relevant milestone. In the event of default, PsyProtix shall automatically repurchase a pro rata portion of the Escrow Shares from atai ("Repurchase Event") for a purchase price per share equal to the par value of such Escrow Shares. Upon the Repurchase Event, the Escrow Shares are released from escrow to PsyProtix and thereafter cancelled. The Repurchase Event is the sole remedy upon atai's failure to make the payment for the milestone shares. In addition, prior to the occurrence of the earlier of a certain milestone event or reaching of the Company's capital contribution threshold of $5.0 million, PsyProtix will issue additional shares of common stock to Chymia to maintain Chymia's current ownership percentage. This anti-dilution right was concluded to be embedded in the common shares held by Chymia.

Immediately following the closing of the PsyProtix Purchase Agreement, PsyProtix loaned $0.1 million to Chymia in exchange for a duly executed promissory note (the "Chymia Note"). The Chymia Note shall accrue interest at a 5% rate per annum until payment in full. The aggregate principal amount of $0.1 million, together with all accrued and unpaid interest and all other amounts payable are due to be paid on the date that is the earlier of (i) five years from the promissory note agreement date or (ii) the occurrence of a liquidation event or a deemed liquidation event (as defined in the PsyProtix's certificate of incorporation). As of December 31, 2022, the Chymia Note was $0.1 million and included as a component of long-term notes receivable—related parties on the consolidated balance sheets.

The PsyProtix Purchase Agreement provided the Company unilateral rights to control all decisions related to the significant activities of PsyProtix. The Company concluded that PsyProtix was not considered a business based on its assessment under ASC 805 and accounted for the Company's acquisition in PsyProtix as an initial consolidation of a VIE that is not a business under ASC 810 (See Note 4). The assets acquired, liabilities assumed, and noncontrolling interest in the transaction were measured based on their fair values. The Company did not recognize a gain or a loss in connection with the consolidation of PsyProtix as the fair value of the consideration paid of $0.1 million was equivalent to the fair value of the identifiable assets acquired of $0.1 million.

In October 2021, pursuant to the Board consent letter and the PsyProtix Purchase Agreement discussed above, the Company released a payment in the amount of $0.5 million upon the achievement of specified clinical milestones. Accordingly, 500,000 Series A Preferred Stock was released from the escrow account to atai. The Company's equity ownership interest in PsyProtix remained unchanged as the PsyProtix Escrow Shares were already deemed issued, outstanding and legally owned by atai.

Psyber, Inc.

Psyber is a globally based startup focused on the development of brain-computer interface-enabled digital therapeutics for treating mental health issues. Psyber was created as a joint venture between the Company and the founders of Psyber. In February 2021, pursuant to a Series A Preferred Stock Purchase Agreement (the "Psyber Purchase Agreement"), the Company acquired shares of Psyber's Series A preferred stock in exchange for an initial payment of $0.2 million in cash. In addition, pursuant to the Psyber Purchase Agreement, the Company agreed to make aggregate payments to Psyber of up to $1.8 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding to Psyber. The Psyber Purchase Agreement resulted in the Company holding a 75.0% voting interest and the founders of Psyber jointly holding a 25.0% voting interest in Psyber. In connection with the Company's agreement for additional funding, Psyber issued the corresponding Series A preferred shares to the Company provided that the shares are held in an escrow account (the "Psyber Escrow Shares"). The Psyber Escrow Shares will be released, from time to time, to the Company upon Psyber achieving certain milestones as defined in the Psyber Purchase Agreement with cash payments to be made by the Company. In addition, the Company has the right, but not the obligation, to make payment for the certain Psyber Escrow Shares at any time, regardless of the achievement of any milestones. The Psyber Escrow Shares have voting and all other rights until an event of default occurs where the Company fails to make a payment within 10 days following the written notice of the achievement of the relevant milestone. In the event of default, Psyber shall automatically repurchase a pro rata portion of the Escrow Shares from atai ("Repurchase Event") for a purchase price per share equal to the par value of such Escrow Shares. Upon the Repurchase Event, the Escrow Shares are released from escrow to Psyber and thereafter cancelled. The Repurchase Event is the sole remedy upon atai's failure to make the payment for the milestone shares. In addition, prior to the occurrence of the earlier of a certain milestone event or reaching of the Company's capital contribution threshold of $2.0 million, Psyber will issue additional shares of common stock to the founders of Psyber to maintain the founders' current ownership percentage. This anti-dilution right was concluded to be embedded in the common shares held by the founders of Psyber.

The Psyber Purchase Agreement provided the Company unilateral rights to control all decisions related to the significant activities of Psyber. The Company concluded that Psyber was not considered a business based on its assessment under ASC 805 and accounted for the Company's acquisition in Psyber as an initial consolidation of a VIE that is not a business under ASC 810 (See Note 4). The assets acquired, liabilities assumed, and noncontrolling interest in the transaction were measured based on their fair values. The Company recognized a de minimis gain for the year ended December 31, 2021. The gain was calculated as the sum of the consideration paid of $0.2 million, less the fair value of identifiable net assets acquired of $0.2 million.

InnarisBio, Inc.

In February 2021, the Company jointly formed 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. In March 2021, pursuant to a Series A Preferred Stock Purchase Agreement (the "InnarisBio Purchase Agreement"), the Company acquired shares of InnarisBio's Series A preferred stock in exchange for an initial payment of $1.1 million in cash. In addition, pursuant to the InnarisBio Purchase Agreement, the Company agreed to make aggregate payments to InnarisBio of up to $3.9 million upon the achievement of specified clinical milestones to complete the purchase of the shares and provide additional funding to InnarisBio. The InnarisBio Purchase Agreement resulted in the Company holding an 82.0% voting interest and UniQuest holding a 18.0% voting interest in InnarisBio. In connection with the Company's agreement for additional funding, InnarisBio issued the corresponding Series A preferred shares to the Company provided that the shares are held in an escrow account (the "InnarisBio Escrow Shares"). The InnarisBio Escrow Shares will be released, from time to time, to the Company upon InnarisBio achieving certain milestones as defined in the InnarisBio Purchase Agreement with cash payments to be made by the Company. In addition, the Company has the right, but not the obligation, to make payment for the InnarisBio Escrow Shares at any time, regardless of the achievement of any milestones. The InnarisBio Escrow Shares have voting and all other rights until an event of default occurs where the Company fails to make a payment within 10 days following the written notice of the achievement of the relevant milestone. In the event of default, InnarisBio shall automatically repurchase a pro rata portion of the Escrow Shares from atai ("Repurchase Event") for a purchase price per share equal to the par value of such Escrow Shares. Upon the Repurchase Event, the Escrow Shares are released from escrow to InnarisBio and thereafter cancelled. The Repurchase Event is the sole remedy upon atai's failure to make the payment for the milestone shares.

The InnarisBio Purchase Agreement provided the Company unilateral rights to control all decisions related to the significant activities of InnarisBio. The Company concluded that InnarisBio was not considered a business based on its assessment under ASC 805 and accounted for the Company's acquisition in InnarisBio as an initial consolidation of a VIE that is not a business under ASC 810 (See Note 4). The assets acquired, liabilities assumed, and noncontrolling interest in the transaction were measured based on their fair values. The Company recognized a de minimis loss on consolidation for the year ended December 31, 2021. The loss was calculated as the sum of the consideration paid of $1.1 million, the fair value of the noncontrolling interest issued of $0.9 million, less the fair value of identifiable net assets acquired of $2.0 million. The fair value of the contingent milestone payments of $0.1 million was included in the total purchase consideration for the noncontrolling interest and recognized as a liability by InnarisBio at the date of acquisition. The fair value of the IPR&D acquired of $1.0 million was reflected as acquired in-process research and development expense on the consolidated statements of operations for the year ended December 31, 2021 as it had no alternative future use at the time of the acquisition.

Neuronasal, Inc.

Neuronasal, Inc. (“Neuronasal”) is developing a novel intranasal formulation of N-acetylcysteine for acute mild traumatic brain injury. The Company first acquired investments in Neuronasal in December 2019 pursuant to a Preferred Stock Purchase Agreement (the “Neuronasal PSPA”). In December 2019, in connection with the original purchase of the preferred shares, Neuronasal and the Company entered into the Secondary Sale and Put Right Agreement (the “Neuronasal Secondary Sale Agreement”), whereby upon the achievement of certain contingent development milestones, existing common shareholders have the right to sell and the Company has the option but not the obligation to purchase additional shares of common stock at a price determined based on the fair market value per share on the date of exercise. These options that will allow the Company to purchase additional common shares are contingent upon the exercise of the options by Neuronasal’s common shareholders to sell shares to the Company. On March 10, 2021, pursuant to the Neuronasal PSPA, the Company purchased additional Series A preferred shares for approximately $0.8 million based on the achievement of certain development milestones. Also, pursuant to the Neuronasal Secondary Sale Agreement, the Company purchased additional common shares for approximately $0.3 million. On May 17, 2021, pursuant to the Neuronasal PSPA the Company exercised its option to purchase additional shares of Series A preferred stock of Neuronasal for an aggregate cost of $1.0 million. The additional purchase on May 17, 2021 resulted in the Company obtaining an aggregate 56.5% ownership interest in Neuronasal, including the Company’s previously acquired investments in Neuronasal’s common and preferred stock, and provided the Company with control of Neuronasal’s board of directors and the unilateral rights to control all decisions related to the significant activities of Neuronasal. Prior to May 17, 2021, the Company accounted for its investments in Neuronasal’s common stock under the equity method and Neuronasal’s preferred stock under the measurement alternative (See Note 5). Following the closing of this acquisition on May 17, 2021, the results of Neuronasal have been consolidated in the Company’s consolidated financial statements.

The Company concluded that Neuronasal was not considered a business based on its assessment under ASC 805 and accounted for the Company’s acquisition in Neuronasal as an initial consolidation of a variable interest entity (“VIE”) that is not a business under ASC 810 (See Note 4). The assets acquired, liabilities assumed, and noncontrolling interest in the transaction were measured based on their fair values. The Company recognized a gain of $3.5 million for the year ended December 31, 2021. The gain was calculated as the sum of the consideration paid of $1.0 million, the fair value of the noncontrolling interest issued of $3.0 million, the carrying value of the Company’s investments in Neuronasal’s common stock and preferred stock prior to May 17, 2021 of $0.8 million, less the fair value of identifiable net assets acquired of $8.3 million. The fair value of the IPR&D acquired of $8.0 million was reflected as acquired in-research and development expense on the consolidated statements of operations for the year ended December 31, 2021 as it had no alternative future use at the time of the acquisition.

TryptageniX, Inc.

TryptageniX, Inc. ("TryptageniX"), a Delaware corporation, was incorporated by CB Therapeutics, Inc. (“CBT”) on November 17, 2021, for the purpose of developing and commercializing Intellectual Property (“IP”) and to develop innovative biosynthetic methods to manufacture bioidentical, clinically relevant compounds, including psychoactive compounds which are highly difficult to produce sustainability through traditional methods. TryptageniX will generate New Chemical Entities (“NCE"). In December 2021, pursuant to the Stock Purchase Agreement (TryptageniX-ATAI Stock Purchase Agreement"), atai acquired Class A Common Stock in exchange for $2.0 million and received a certificate representing additional Class A Common Stock to be held in escrow ("Escrow Shares") by TryptageniX to be released upon achievement of specified clinical milestones and corresponding milestone payments. The TryptageniX-ATAI Stock Purchase Agreement resulted in the Company holding a 65% equity ownership interest and CBT holding a 35% equity ownership interest in TryptageniX. The Escrow Shares will be released, from time to time, to the Company upon TryptageniX achieving certain milestones as defined in the TryptageniX Purchase Agreement with cash payments to be made by the Company. Notwithstanding anything to the contrary, atai shall be the owner of the Escrow Shares and has the right, but not the obligation, to make payment for the Escrow Shares at any time, regardless of the achievement of any milestones. The Escrow Shares have voting and all other rights until an event of default occurs where the Company fails to make a payment within 10 days following the written notice of the achievement of the relevant milestone. In the event of default, TryptageniX shall automatically repurchase a pro rata portion of the Escrow Shares from atai (“Repurchase Event”) for a purchase price per share equal to the par value of such Escrow Shares. Upon the Repurchase Event, the Escrow Shares are released from escrow to TryptageniX and thereafter cancelled. The Repurchase Event is the sole remedy upon atai’s failure to make the payment for the milestone shares.

On December 3, 2021, the Company made an additional payment of $1.0 million to CBT for the first installment of a $2.0 million exclusivity fee to become a party to the TryptageniX-ATAI Stock Purchase Agreement. The fee represents the exclusive right to the CBT technology and know-how defined in the TryptageniX Stockholders Agreement. The remaining installment of $1.0 million shall be paid no later than the second anniversary of the acquisition date, either in cash or in common shares of atai.

The TryptageniX-ATAI Stock Purchase Agreement provided the Company unilateral rights to control all decisions related to the significant activities of TryptageniX. The Company concluded that the acquired assets and activities of TryptageniX did not constitute a business based on its assessment under ASC 805 and accounted for the acquisition as an initial consolidation of a VIE that is not a business under

ASC 810 (See Note 4). The assets acquired, liabilities assumed, and noncontrolling interest in the transaction were measured based on their fair values. The Company did not recognize a gain or a loss in connection with the consolidation of TryptageniX as the fair value of the consideration paid of $1.0 million was equivalent to the fair value of identifiable net assets acquired of $6.5 million, less the fair value of the noncontrolling interest issued of $3.9 million, fair value of the contingent consideration of $0.9 million, and fair value of liability for seller financing of $0.8 million. The Company elected to expense the entire fair value of the acquired IPR&D asset of $6.5 million as it has no alternative use at the acquisition date.

All acquisitions discussed above were considered as asset acquisitions and no goodwill was recognized upon consolidation.

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 56.5% 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 and the Company deconsolidated Neuronasal in November 2022 because it determined that it no longer was the primary beneficiary of Neuronsasal as it no longer had the power to direct the significant activities of 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 recognized as a component of other income 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. In connection with the deconsolidation of Neuronasal, the Company concluded that a loan loss has been incurred and the loan assets were impaired accordingly. The Company recognized an impairment of loan receivable of $0.9 million 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, 2022.

As of December 31, 2022 and December 31, 2021, the Company has accounted for the following consolidated investments as VIEs, excluding the wholly owned subsidiaries:

Consolidated Entities	Relationship as of December 31, 2022	Relationship as of December 31, 2021	Date Control Obtained	Ownership % December 31, 2022	Ownership % December 31, 2021
Perception Neuroscience Holdings, Inc.	Controlled VIE	Controlled VIE	November 2018	58.9%	58.9%
Kures, Inc.	Controlled VIE	Controlled VIE	August 2019	64.5%	54.1%
EntheogeniX Biosciences, Inc.	Controlled VIE	Controlled VIE	November 2019	80.0%	80.0%
DemeRx IB, Inc.	Controlled VIE	Controlled VIE	December 2019	59.5%	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.	Controlled VIE	Controlled VIE	February 2021	75.0%	75.0%
InnarisBio, Inc.	Controlled VIE	Controlled VIE	March 2021	82.0%	82.0%
Neuronasal, Inc.	— [(1)]	Controlled VIE	May 2021	—	56.5%
TryptageniX Inc.	Controlled VIE	Controlled VIE	December 2021	65.0%	65.0%

[(1)] As discussed in Note 3, the Company deconsolidated Neuronsal, Inc. in November 2022.

As of December 31, 2022 and December 31, 2021, 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 September 2021, the Company executed an amendment to the Stockholders Agreement and Contribution and Subscription Agreement ("EntheogeniX Amendment") between atai, EntheogeniX and Cyclica, in which atai agreed to purchase additional Class A common stock for an aggregate purchase price of $0.5 million. In February and September 2022, pursuant to the EntheogeniX Amendment, atai 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 the Class A common stock purchase. As of December 31, 2022 and December 31, 2021, the Company owned 80% of the outstanding common stock of EntheogeniX.

The purchase of additional Class A common stock was deemed to be a reconsideration event. The Company determined that EntheogeniX is still considered a VIE subsequent to the additional Class A common stock purchase as EntheogeniX does not have sufficient equity at risk to carry out its principal activities without additional subordinated financial support.

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all 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

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all consolidated VIEs as of December 31, 2021 (in thousands):

	Perception	Kures	EntheogeniX	DemeRx IB	Recognify	PsyProtix	Psyber	InnarisBio	Neuronasal	TryptageniX
Assets:										
Current assets:										
Cash	$ 23,099	$ 1,048	$ 198	$ 8,511	$ 2,519	$ 512	$ 542	$ 1,487	$ 95	$ 2,000
Unbilled receivable	64	—	—	—	—	—	—	—	—	—
Prepaid expenses and other current assets	1,138	104	—	70	4	1	—	62	207	—
Total current assets	24,301	1,152	198	8,581	2,523	513	542	1,549	302	2,000
Property and equipment, net	1	—	—	—	—	—	—	—	—	—
Long term notes receivable	—	—	—	1,075	—	104	—	—	—	—
Other assets	—	—	—	—	—	—	99	—	—	—
Total assets	$ 24,302	$ 1,152	$ 198	$ 9,656	$ 2,523	$ 617	$ 641	$ 1,549	$ 302	$ 2,000
Liabilities:										
Current liabilities:										
Accounts payable	$ 598	$ 235	$ 53	$ 439	$ 29	$ 51	$ 15	$ —	$ 326	$ —
Accrued liabilities	887	120	9	180	44	50	63	10	749	—
Current portion of contingent consideration liability - related parties	51	—	—	—	—	—	—	—	—	—
Deferred revenue	12	—	—	—	—	—	—	—	—	—
Short-term notes payable	—	—	—	—	—	—	—	—	38	—
Total current liabilities	1,548	355	62	619	73	101	78	10	1,113	—
Contingent consideration liability	1,489	—	—	—	—	—	—	93	—	850
Other non-current liabilities	—	—	—	—	—	—	—	—	336	820
Total liabilities	$ 3,037	$ 355	$ 62	$ 619	$ 73	$ 101	$ 78	$ 103	$ 1,449	$ 1,670

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	Recognify	Psyber	InnarisBio	Neuronasal	TryptageniX	Total
Balance as of December 31, 2020	$ —	$ 4,546	$ —	$ —	$ —	$ —	$ 4,546
Issuance of noncontrolling interests	3,258	—	8	877	392	3,876	8,411
Net income (loss) attributable to noncontrolling interests - common	—	—	(8)	(877)	(392)	(3,876)	(5,153)
Net income (loss) attributable to noncontrolling interests - preferred	1,998	(727)	—	—	—	—	1,271
Comprehensive loss attributable to noncontrolling interests	(24)	—	—	—	—	—	(24)
Balance as of December 31, 2021	$ 5,232	$ 3,819	$ —	$ —	$ —	$ —	$ 9,051

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

Redeemable Noncontrolling Interests

In connection with the consolidation of Kures, Inc. (“Kures”) the Company recognized the shares of Kures common stock and Series A-1 preferred stock held by the founders of Kures as redeemable noncontrolling interests as they contain embedded put options that are exercisable by the founders following a successful completion of a future event, which is not solely within the control of the Company.

In connection with the consolidation of DemeRx IB, the Company recognized common stock held by DemeRx as redeemable noncontrolling interests as they are redeemable upon the occurrence of events that are not solely within the control of the Company.

In connection with the consolidation of Neuronasal, the Company recognized the shares of Neuronasal common stock held by the founders of Neuronasal as redeemable noncontrolling interests as they contain embedded put options that are exercisable by the founders following a successful completion of a future event, which is not solely within the control of the Company. As discussed in Note 3, the Company deconsolidated Neuronasal in November 2022.

The redeemable noncontrolling interests were initially measured at fair value upon issuance and are redeemable at fair value at the holder’s option upon the successful completion or occurrence of future events. As of December 31, 2022 and December 31, 2021, the Company did not adjust the carrying value of the redeemable noncontrolling interests based on their estimated redemption values since it was not probable that the events that would allow the shares to become redeemable would occur. Subsequent adjustments to increase or decrease the carrying values of the redeemable noncontrolling interests to their estimated redemption values will be made if and when it becomes probable that such events will occur.

As of December 31, 2022 and December 31, 2021, the balance of redeemable noncontrolling interests in temporary equity on the consolidated balance sheets was zero. There was no redeemable noncontrolling interest activity during the year ended December 31, 2022.

The following table provides a rollforward of the redeemable noncontrolling interests balance activity (in thousands):

	Neuronasal	Total
Balance as of December 31, 2020	$ —	$ —
Issuance of redeemable noncontrolling interests	2,555	2,555
Net loss attributable to redeemable noncontrolling interests - common	(2,555)	(2,555)
Balance as of December 31, 2021	$ —	$ —

Non-consolidated VIEs

The Company evaluated the nature of its investments in Innoplexus AG ("Innoplexus"), DemeRx NB, Inc. ("DemeRx NB") and IntelGenx and determined that the investments are VIEs as of the date of the Company's initial investment through December 31, 2022. 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, 2022 and December 31, 2021.

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 or the measurement alternative included within ASC 321 (See Note 5). As of December 31, 2022, the Company's maximum exposure for its non-consolidated VIEs was $6.8 million relating to the carrying values in other investments and other investments held at fair value and $7.2 million relating to the carrying value in long term notes receivable – related party. As of December 31, 2021, the Company's maximum exposure for its non-consolidated VIEs was $11.6 million relating to the carrying values in its other investments and $3.8 million relating to the carrying value in short term notes receivable—related party.

5. Equity Method Investments and Other Investments

Equity Method Investments

As of December 31, 2022 and December 31, 2021, the Company accounted for the following investments in the investee's common stock under the equity method (amounts in thousands):

		As of December 31, 2022		As of December 31, 2021	
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	22.4%	—	22.8%	16,131
GABA Therapeutics, Inc	November 2020	7.5% (1)	—	7.5% (1)	—
Total			$ —		$ 16,131

(1)The Company is deemed to have significant influence over this entity through its total ownership interest in the entity's equity, including the Company's investment in the respective entity's preferred stock, described below in Other Investments. The Company's total ownership interest, considering both preferred and common stock is 54.7%.

COMPASS Pathways plc

COMPASS Pathways plc ("COMPASS") is a mental health care company dedicated to pioneering the development of a new model of psilocybin therapy with its product COMP360. The Company first acquired investments in COMPASS in December 2018.

Equity Investment

Through a series of open market transactions between November 23, 2021 and December 7, 2021, the Company purchased an additional 1,490,111 of COMPASS ADSs at an aggregate purchase price of $47.4 million. The additional shares acquired resulted in an increase in the Company's ownership of COMPASS ADSs to 22.8%. The Company applied the cost accumulation model and recorded its investment at cost. At the date of the investment, a basis difference was identified as the cost basis of the Company's investment in COMPASS exceeded the Company's proportionate share of the underlying net assets in COMPASS. The Company concluded that the basis differences were primarily attributable to COMPASS's IPR&D associated with COMP360, a psilocybin therapy, which COMPASS recently completed a Phase IIb clinical trial for. As the Company's investment in COMPASS did not meet the definition of a business due to substantially all of the estimated fair value of the gross assets being concentrated in COMP360 and the associated IPR&D, the basis differences were attributable to the IPR&D with no alternative future use and were immediately expensed at the time of the additional investment. As of

December 31, 2022, the Company owned 22.4% of COMPASS ADS. Based on quoted market prices, the market value of the Company's ownership in COMPASS was $76.8 million and $211.4 million as of December 31, 2022 and 2021, respectively.

Upon the completion of the COMPASS IPO, the Company was deemed to have significant influence over COMPASS primarily through its ownership interest in COMPASS' equity and the Company's representation on COMPASS board of directors. Following the COMPASS 2022 annual shareholder meeting, the Company no longer is represented on the COMPASS board. However, the Company maintains significant influence through its ownership interest. Accordingly, the Company's investment in COMPASS' ADS was accounted for in accordance with the equity method through December 31, 2022

During the years ended December 31, 2022 and 2021, the Company recognized its proportionate share of COMPASS' net loss of $10.1 million and $10.5 million, respectively, as losses from investments in equity method investees, net of tax on the consolidated statements of operations.

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, 2022 and December 31, 2021, 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, 2022	December 31, 2021
GABA Therapeutics, Inc.	$ 5,387	$ 10,260
DemeRx NB, Inc.	1,024	1,024
Juvenescence Limited	344	344
Total	$ 6,755	$ 11,628

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. Although the Company's investment in Juvenescence Limited ("Juvenescence") is in common stock, it is not able to exercise significant influence over the operating and financial decisions of Juvenescence. The Company concluded that its ownership interests in above Other Investments do not have a readily determinable fair value and are accounted for under the measurement alternative. Under the measurement alternative, the Company measured its other investments at cost, less any impairment, plus or minus, if any, observable price changes in orderly transactions for an identical or similar investment of the same issuer.

During the years ended December 31, 2022 and 2021 there were no observable changes in price recorded related to the Company's Other Investments.

During the years ended December 31, 2022 and 2021, the Company evaluated all of its other investments to determine if certain events or changes in circumstance during these time periods in 2022 and 2021 had a significant adverse effect on the fair value of any of its investments in non-consolidated entities. Based on this analysis, the Company did not note any impairment indicators associated with the Company's Other Investments.

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, 2022 and 2021, 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, 2022 and 2021.

The carrying value of the Company's investment in Innoplexus was zero as of December 31, 2022 and December 31, 2021.

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. 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 as discussed below.

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, 2022. Accordingly, 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 discussed below. During the years ended December 31, 2022 and 2021, the Company recognized its proportionate share of GABA's net loss of $5.9 million and $5.0 million, respectively, as losses from investments in equity method investees, net of tax on the consolidated statements of operations.

Preferred Stock Investment

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. On May 15, 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. 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. As of December 31, 2022 and 2021, the investment in GABA's preferred stock was recorded in Other Investments on the consolidated balance sheets under the measurement alternative under ASC 321.

Pursuant to the GABA PSPA, the Company is 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. On April 13, 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. On May 21, 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. 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, 2021, the Company completed the purchase of the additional shares of Series A preferred stock for $10.0 million pursuant to the GABA PSPA. 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 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. In August 2019, pursuant to the Right of First Refusal and Co-Sale Agreement, the Company 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.

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.

Neuronasal, Inc.

Neuronasal is developing a novel intranasal formulation of N-acetylcysteine ("NAC") for acute mild traumatic brain injury.

Common Stock Investment

In October 2020, upon the achievement of certain development milestones, the Company made a cash contribution of $0.3 million in exchange for 9.8% of the outstanding common stock of Neuronasal. The carrying value of the investment in Neuronasal common stock was reduced to zero as of December 31, 2020 due to IPR&D charges with no alternative future use. Accordingly, Neuronasal's net losses attributable to the Company was determined based on the Company's ownership percentage of preferred stock in Neuronasal and recorded to the Company's investments in Neuronasal preferred stock discussed below.

On March 10, 2021, upon the achievement of certain development milestones, the Company made another cash contribution of $0.5 million in exchange for 10.8% of the outstanding common stock of Neuronasal. The Company recorded its investment in Neuronasal common stock at the carrying cost basis of $0.5 million. At the date of the investment, a basis difference was identified as the cost basis of the Company's investment in Neuronasal exceeded the Company's proportionate share of the underlying net assets in Neuronasal. The Company concluded that the basis differences were primarily attributable to Neuronasal's IPR&D associated with Neuronasal's novel intranasal formulation of NAC. As the Company's investments in Neuronasal did not meet the definition of a business due to substantially all of the estimated fair value of the gross assets being concentrated in NAC, the basis differences were attributable to the IPR&D with no alternative future use, and were immediately expensed on the dates of investments. The Company's proportionate share of the basis difference exceeded its carrying value of the equity method investment in Neuronasal and as a result, the March 2021 equity investment balance of $0.5 million was reduced to zero. For the three months ended March 31, 2021, the Company recognized losses from investments in equity method investees, net of tax of $0.5 million in association with the basis difference charge in the Company's consolidated statements of operations.

The Company was deemed to have significant influence over Neuronasal through its total ownership interest in Neuronasal's equity through the acquisition date of May 17, 2021 (see Note 3), including the Company's investment in Neuronasal's preferred stock, and the Company's noncontrolling representation on Neuronasal's board of directors. Accordingly, the Company's investment in Neuronasal's common stock was accounted for in accordance with the equity method. Immediately prior to the acquisition, the Company recognized its proportionate share of Neuronasal's year to date net loss of $1.0 million, as losses from investments in equity method investees, net of tax on the consolidated statements of operations.

The Company's investment in Neuronasal's preferred stock did not meet the criteria for in-substance common stock. As such, the investment in Neuronasal's preferred stock was accounted for under the measurement alternative as discussed below.

Preferred Stock Investment

In December 2019, Neuronasal and the Company entered into the Neuronasal PSPA and the Neuronasal Secondary Sale Agreement, whereby Neuronasal issued shares of its Series A preferred stock to the Company at a price of approximately $0.5 million. At closing, the Company had a less than 20% of ownership interest in Neuronasal and a noncontrolling representation on the board. In October 2020, pursuant to the Neuronasal PSPA, the Company purchased additional Series A preferred shares at a price of approximately $0.8 million. The investment in Neuronasal preferred shares was recorded in Other Investments on the consolidated balance sheets under the measurement alternative under ASC 321 as of December 31, 2022 and 2021.

In October 2020, pursuant to the Neuronasal PSPA, the Company purchased additional Series A preferred shares at a price of approximately $0.8 million upon the achievement of a specified contingent clinical development milestone. On March 10, 2021, pursuant to the Neuronasal PSPA, the Company purchased additional Series A preferred shares for approximately $0.8 million based on the achievement of certain development milestones.

On May 17, 2021, pursuant to the Neuronasal PSPA and the Neuronasal Secondary Sale Agreement, the Company, at its sole option, purchased additional shares of Series A preferred stock of Neuronasal for an aggregate cost of $1.0 million. Upon the closing of the purchase on May 17, 2021, the Company obtained a controlling financial interest in Neuronasal. The Company derecognized its other investments in Neuronasal and began to consolidate the operations of Neuronasal into its financial statements. See Note 3, “Acquisitions and Dispositions” for further discussion.

In November 2022, pursuant to the Termination Agreement, the Company deconsolidated Neuronasal. See Note 3, "Acquisitions and Dispositions" for further discussion.

DemeRx NB

In December 2019, the Company jointly formed DemeRx NB with DemeRx. DemeRx and DemeRx NB entered into a Contribution Agreement whereby DemeRx 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.

Pursuant to the DemeRx NB PSPA, the Company also has the option but not the obligation to purchase additional shares of DemeRX NB's Series A preferred stock at a purchase price of up to an aggregate of $19.0 million with the same price per share as its initial investment in December 2019. As of December 31, 2022, the Company has not exercised its option to purchase any shares of Series A preferred stock of DemeRx NB.

Other Investments Held at Fair Value

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”). On May 14, 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.

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 year ended December 31, 2022, research and development services performed in relation to the Strategic Development Agreement were $0.5 million, which was applied as a reduction in research and development expense in accordance with the Strategic Development Agreement. No material research and development services were performed during the year ended December 31, 2021.

The Company has significant influence over IntelGenx through ownership interest in IntelGenx's equity and the Company's 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 Additional Units Warrant, (collectively the "Warrants") 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 is 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 and the Warrants as a component of other income (expense), net in the consolidated statement of operations. The carrying amount of the investment was reduced to zero as of December 31, 2021 and during the year ended December 31, 2022, the Company recognized a $0 mark-to-market ("MTM") gain/loss in the consolidated statement of operations. The carrying value of the investment remained at zero as of December 31, 2022 and 2021, respectively.

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, 2022	
	COMPASS	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

	December 31, 2021	
	COMPASS	GABA
Current assets	$ 295,300	$ 7,673
Non-current assets	5,598	—
Total assets	$ 300,898	$ 7,673
Current liabilities	$ 15,107	$ 199
Non-current liabilities	1,379	—
Total liabilities	$ 16,486	$ 199

Statements of operations

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

	Year Ended December 31, 2021		
	COMPASS	Neuronasal[1]	GABA
Revenue	$ —	$ —	$ —
Loss from continuing operations	$ (83,221)	$ (985)	$ (4,216)
Net loss	$ (71,742)	$ (985)	$ (4,216)

(1)Results from operations for Neuronasal are through May 17, 2021 at which point the entity is consolidated.

6. Notes Receivable

Long Term Notes Receivable – related party

Loan to IntelGenx Corp.

On March 8, 2021, the Company and IntelGenx entered into a loan agreement (the "IntelGenx Loan Agreement") under which the Company provided a loan to IntelGenx for an aggregate principal amount of $2.0 million (the "March Term Loan"). Pursuant to the loan agreement, IntelGenx may, by written notice, request an advance up to an additional $0.5 million as an additional term loan if no event of default has occurred as defined in the loan agreement. On May 11, 2021, the Company paid an additional advance of $0.5 million as an additional term loan (the "May Term Loan", and together with the March Term Loan the "Term Loans"). The Term Loans were originally due to mature 120 days following the special shareholder meeting of IntelGenx Tech Corp. to approve an additional investment in IntelGenx Tech Corp. by the Company ("Maturity Date"). On May 14, 2021, the Company amended the loan agreement under which the Maturity Date will be the first business day following the first closing of a subscription for additional units if the proceeds from such subscription amount to at least $3.0 million. The loan bears an annualized interest rate of 8% and such interest is accrued daily. The principal amount of the Term Loans plus any accrued interest shall become due and payable on the Maturity Date. On September 14, 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, up to a total of $8.5 million. The additional loan amount of $6.0 million shall be funded via two separate tranches of $3.0 million each in the beginning of 2022 and 2023 respectively, subject to certain conditions. In addition, the amendment further extended the Maturity Date to January 5, 2024. The first tranche was funded in January 2022.

Pursuant to the terms of the Term Loans, upon the occurrence of an event of default, the Company may accelerate the Term Loans and declare the principal and any accrued and unpaid interests of the Term Loans to be immediately due and payable. In addition, IntelGenx may prepay the Term Loans in whole or in part at any time without premium or penalty. Any prepayment of the principal shall be accompanied by a payment of interest accrued to date thereon. The Company concluded that these embedded features do not meet the criteria to be bifurcated and separately accounted for as derivatives.

The Company recorded the Term Loans at cost, which included the principal balance of the note and accrued interest in Long term notes receivables – related parties on its consolidated balance sheets. As of December 31, 2022 and 2021, the Term Loans have an outstanding balance of $5.5 million and $2.5 million, respectively. During the year ended December 31, 2022 the Company recognized $0.4 million in interest income. During the year ended December 31, 2021, the interest income recognized in connection with the Term Loans was immaterial. The Company assesses the Term Loans for impairment and records an impairment loss when information becomes available that indicates it is probable that the Term Loans have been impaired and the amount of the loss can be reasonably estimated. As of December 31, 2022, no impairment indicators were present.

As of December 31, 2022, the fair value of the term loan was $5.5 million, which is categorized as Level 3 in the fair value hierarchy.

Investment in DemeRx Promissory Note—Related Party

On January 3, 2020, DemeRx IB loaned to DemeRx Inc. $1.0 million pursuant to the terms of a separate Promissory Note ("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"). Upon occurrence of any deemed liquidation event, no proceeds generated from such event will be distributed to DemeRx until any and all outstanding amounts

under the DemeRx Note have been repaid in full. Pursuant to the terms of the DemeRx Note, DemeRx 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.

The Company recorded the DemeRx Note at cost which included the principal balance of the DemeRx Note and accrued interest, net of any payments received, on its consolidated balance sheets. As of December 21, 2022, and 2021, the DemeRx Note had an outstanding balance of $1.1 million and $1.1 million, respectively. For the year ended December 31, 2021, the Company recognized an immaterial amount of interest income associated with the DemeRx Note as a component of Other Income in the consolidated statements of operations. For the year ended December 31, 2022, the Company did not earn any interest income associated with the DemeRx Note.

7. Fair Value Measurement

The following table presents information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation (in thousands):

	Fair Value Measurements as of 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:				
U.S. Treasuries	—	—	—	—
Commercial Paper	—	5,958	—	5,958
Corporate Notes/Bonds	—	17,719	—	17,719
U.S. Government Agencies	—	58,819	—	58,819
Other investment at fair value	—	—	—	—
	$ 72,334	$ 82,496	$ —	$ 154,830
Liabilities:				
Contingent consideration liability - related parties	$ —	$ —	953	$ 953
Warrant Liability	—	—	—	—
	$ —	$ —	$ 953	$ 953

	Fair Value Measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Cash & Money market funds	$ 271,856	$ —	$ —	$ 271,856
Investment in securities at fair value:				
U.S. Treasuries	—	—	—	—
Commercial Paper	—	—	—	—
Corporate Notes/Bonds	—	—	—	—
U.S. Government Agencies	—	—	—	—
Other investment at fair value	—	—	—	—
	$ 271,856	$ —	$ —	$ 271,856
Liabilities:				
Contingent consideration liability - related parties	$ —	$ —	$ 2,483	$ 2,483
Warrant liability	—	—	336	336
	$ —	$ —	$ 2,819	$ 2,819

Investment Securities Portfolio - Fair Value Option

The Company elected the fair value option for the securities in the 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.

Contingent Consideration Liability—Related Parties—Perception, InnarisBio, and TryptageniX

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"), InnarisBio and TryptageniX. 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:

- the probability and timing of achieving the specified milestones and royalties as of each valuation date,
- the probability of executing the license agreement,
- the expected first year of revenue, and
- market-based discount rates

The fair value of the contingent milestone and royalty liabilities for InnarisBio was estimated to be $0.1 million and $0.1 million as of December 31, 2022 and 2021, respectively.

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, 2022 and 2021, 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 $1.5 million as of December 31, 2022 and 2021, respectively.

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

		December 31, 2022	December 31, 2021
Valuation Technique	**Significant Unobservable Inputs**	**Input Range**	**Input Range**
Discounted cash flow	Milestone contingent consideration:		
	Discount rate	13.1%	11.4%
	Probability of the milestone	10.0% - 21.0%	51.9%
Discounted cash flow with SBM	Royalty contingent consideration:		
	Discount rate for royalties	20.0% - 21.1%	19.2% - 20.1%
	Discount rate for royalties on milestones	12.3% - 13.4%	10.9% - 11.8%
	Probability of success rate	10.1% - 21.0%	26.5% to 100.0%

The fair value of the contingent liability for TryptageniX was estimated to be $0.2 million and $0.9 million as of December 31, 2022 and 2021, respectively. The contingent liability is comprised of R&D 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.

Warrant Liability

The warrant liability in the table above relates to issued and outstanding warrants to purchase shares of Neuronasal's common stock acquired in connection with the acquisition of Neuronasal. The warrants were classified within other liabilities in the accompanying consolidated balance sheet as the underlying common stock was determined to be contingently, but not currently, redeemable. The warrant liability was recorded at fair value utilizing the Black-Scholes option pricing model. As summarized below, key inputs in connection with the Black-Scholes option pricing model represent Level 3 measurements within the fair value hierarchy. 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 warrant, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying common stock. The Company adjusted the carrying value of the warrant to its estimated fair value at each reporting date, with any related increase or decrease in the fair value recorded as a component of other income (expense), net in the consolidated statement of operations.

The fair value of the warrant liability was estimated to be $0.3 million as of December 31, 2021.

The following table summarizes significant unobservable inputs that are included in the valuation of the warrant lability as of December 31, 2021:

	December 31, 2021
Stock Price	$ 50.56
Expected Volatility	100 %

As discussed in Note 3, the Company deconsolidated Neuronasal in November 2022. The Company remeasured the Neuronasal warrant liability at fair value immediately prior to conversion in November 2022. The fair value of the Neuronasal warrant liability was determined to be de minimis on November 9, 2022, resulting in a $0.3 million unrealized gain immediately prior to deconsolidation.

IntelGenx Common Stock, Initial Warrants and Additional Units Warrant

The Company's investment in IntelGenx consists of Common Shares, Initial Warrants and Additional Unit Warrants (collectively the "Warrants"). The Company determined Warrants do not meet the definition of derivative instrument per ASC 815. The Company has classified the Common Shares as Level 2 assets and the Initial Warrants and Additional Unit Warrants as Level 3 assets in the fair value hierarchy. The Company determined that the initial aggregate fair value 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 Units Warrant 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 Warrants are measured at fair value on a quarterly basis and any changes in the fair value will be recorded as a component of other income (expense), net in the consolidated statement 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, 2022 and 2021. The Company estimated a DLOM in connection with the valuation of the Common Shares at initial recognition and as of December 31, 2022 and 2021 to reflect the restrictions associated with the Common Shares. As of December 31, 2022 and 2021, 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, 2022 and 2021.

The Initial Warrant asset was 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 warrant, 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, 2022 and 2021.

The following table summarizes significant unobservable inputs that are included in the valuation of the Initial Warrants as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Value of Underlying	$ 0.19	$ 0.34
Expected Volatility	100 %	105 %

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, 2022 and 2021.

The following table summarizes significant unobservable inputs that are included in the valuation of the Additional Units Warrant as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Value of Underlying	$ 0.19	$ 0.34
Expected Volatility	100 %	105 %

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):

	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, 2022	December 31, 2021
Prepaid research and development related expenses	$ 4,626	$ 2,692
Tax receivables	5,631	5,406
Prepaid insurance	2,034	3,049
Other	1,745	756
Total	$ 14,036	$ 11,903

9. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued accounting, legal, and other professional fees	$ 3,566	$ 2,667
Taxes payable	2,224	8,137
Accrued external research and development expenses	5,550	861
Accrued payroll	5,260	2,832
Accrued advisory fees	—	169
Other liabilities	706	163
Total	$ 17,306	$ 14,829

10. Debt

Convertible Promissory Notes

2018 Convertible Promissory Notes—Related Parties

Convertible promissory notes—related parties, net of discounts and deferred issuance costs, consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Convertible notes issued in November 2018	—	$ 125
Convertible notes issued in October 2020	415	623
Unamortized discount and deferred issuance costs	—	(5)
Total	$ 415	$ 743

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. For the year ended December 31, 2020, the Company recorded total compensation expense associated with the October 2020 notes issuance of $61.5 million as consideration for services previously provided by the noteholders within general and administrative expense on the consolidated statements of operations.

Conversion of 2018 Convertible Promissory Notes - Related Parties

As described in Note 1, 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.

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.

Perception Convertible Promissory Notes

On March 16, 2020, Perception entered into a convertible promissory note agreement with the Company and other investors, including related parties, which provided for the issuance of convertible notes of $3.9 million (the "Perception Note Purchase Agreement").

The notes bear interest at an annual rate of 5% and were due and payable on June 30, 2022, unless earlier converted (the "Perception March 2020 Notes").

On December 1, 2020, Perception entered into an additional convertible promissory note agreement (the "Perception December 2020 Convertible Note Agreement") with the Company and other investors, including related parties, which provided for the issuance of convertible notes of up to $12.0 million. Pursuant to the Perception December 2020 Convertible Note Agreement, the convertible notes are issued in two tranches: (i) up to $7.0 million under the first tranche funding (the "First Tranche Funding"), with $6.2 million and $0.8 million issued in December 2020 and January 2021, respectively, and (ii) up to an additional $5.0 million under the second tranche funding (the "Second Tranche Funding"), was issued in May 2021.

Under the Second Tranche Funding, Perception issued $4.2 million to the Company, $0.2 million to Apeiron, and $0.3 million to Sonia Weiss Pick and Family, and $0.4 million to other investors.

The notes bear interest at an annual rate of 5% and were due and payable on February 28, 2022, unless earlier converted (the "Perception December 2020 Notes" and together with the Perception March 2020 Notes, the "Perception Convertible Notes").

In the event of a qualified sale of preferred stock resulting in gross proceeds to Perception of at least $5.0 million, all the principal and accrued and unpaid interest under the Perception Convertible Notes will automatically convert, into the same equity securities issued by Perception at a 25% discount from the lowest price of the security issued. In the event that Perception receives upfront proceeds of $5.0 million or more in a licensing transaction, all the principal and accrued and unpaid interest under the Perception convertible notes will automatically convert, into shares of Series A Preferred Stock of Perception at a price per share of $0.75 for the Perception March 2020 Notes and 75% of the fair market value of the Series A Preferred Stock of Perception for the Perception December 2020 Notes. Upon a change in control of Perception, all the principal and accrued and unpaid interest under the Perception Convertible Notes will automatically convert into shares of Series A Preferred Stock of Perception at a price per share of $0.75. The Perception Convertible Notes issued to the Company represent intercompany debt and are eliminated upon consolidation.

The Perception March 2020 Notes contained an embedded conversion features in the event of a qualified financing whereas the Perception December 2020 Notes contained both embedded conversion features in the event of a qualified financing and upon the occurrence of a licensing transaction. The Company concluded that both the embedded conversion features met the definition of embedded derivatives that were required to be bifurcated and accounted for as a separate unit of accounting.

As of December 31, 2020, the Company recorded the fair value of the derivative liabilities of $0.4 million as a liability with the offset being recorded as a debt discount on the issuance dates of the Perception Convertible Notes.

Both the liability and the offsetting debt discount are presented together in convertible promissory notes and derivative liability on the consolidated balance sheets. The resulting debt discount is being amortized to interest expense using the effective interest method over the terms of the Perception Convertible Notes. This interest expense is recorded in other income (expense), net in the consolidated statements of operations. The derivative liabilities are subsequently remeasured to fair value at each reporting date with changes in fair value recognized as a component of other income (expense), net in the consolidated statements of operations.

Upon issuance of the notes under the Second Tranche Funding, the Company recorded the fair value of the derivative liabilities of $0.3 million as a liability with an offset being recorded as a debt discount.

On June 10, 2021, Perception received proceeds of $20.0 million pursuant to the license and collaboration arrangement between Perception and Otsuka Pharmaceutical Co., LTD ("Otsuka") (See Note 16). Upon receipt of the proceeds, the Perception Convertible Notes automatically converted into 6,456,595 shares of Series A preferred stock of Perception pursuant to their original terms. The Company, Sonia Weiss Pick and Family, Apeiron, and other investors received 5,403,791 shares, 440,415 shares, 27,809 shares and 584,580 shares of Perception Series A preferred stock, respectively, upon conversion of the Perception Convertible Notes. The amounts associated with the shares of Perception Series A preferred stock issued to the Company represent intercompany transactions and are eliminated upon consolidation.

The Company remeasured the derivative liability immediately prior to the conversion of the Perception Notes and recorded a net gain of $41,000 resulting from the change in fair value of the derivative liability in June 2021. The conversion of the Perception December 2020 Notes was accounted for as an extinguishment as the notes were converted pursuant to an embedded conversion feature upon a licensing transaction, which was determined to be a redemption feature. Accordingly, the Company recorded a loss on extinguishment of notes of $0.5 million in the consolidated statements of operations for the year ended December 31, 2021. The loss on extinguishment of notes represents the difference between (i) carrying value including derivative liability of the Perception December 2020 Notes of $2.2 million and (ii) the fair value of Perception Series A preferred stock into which the notes converted of $2.7 million. The conversion of the Perception March 2020 Notes was accounted for as a conversion as the notes converted pursuant to a conversion feature. Accordingly, the Company derecognized the carrying amount of the Perception March 2020 notes issued to Sonia Weiss and Family and other investors in the aggregate amount of $0.6 million with an offset to Series A preferred stock, and no gain or loss was recognized. The shares issued upon conversion of the Perception March 2020 and December 2020 Notes issued to the Company represent an intercompany transaction and, therefore, eliminate in consolidation.

As of December 31, 2020, the fair value of the derivative liability was $0.2 million, including an immaterial amount of derivative liability relating to Sonia Weiss Pick and Family.

The Company recognized interest expense of $0.2 million, including amortization of debt discount of $0.2 million during the year ended December 31, 2021. As of December 31, 2021, there was no unamortized debt discount due to the conversion of the Perception Convertible Notes into Series A convertible preferred stock of Perception on June 10, 2021. The debt issuance costs associated with the Perception Convertible Notes were not material.

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 (as amended by that certain First Amendment to Loan and Security Agreement dated as of March 13, 2023, the "Hercules Loan Agreement"). The 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"), available as follows: (i) a term loan advance in the amount of $15.0 million on the Closing Date (the "Tranche 1A Advance"); (ii) at any time after the Closing Date but on or prior to May 1, 2023 (the "Tranche 1B Expiration Date"), term loan advances in an aggregate principal amount of up to $20.0 million (the "Tranche 1B Advances"); (iii) at any time beginning upon the earlier of (A) the Tranche 1B Expiration Date and (B) the date on which all amounts available to be drawn under the Tranche 1B Advances have been drawn and on or prior to December 15, 2023 (the "Tranche 1C Expiration Date"), term loan advances in an aggregate principal amount of up to $25.0 million (the "Tranche 1C Advances" and together with the Tranche 1A Advance and the Tranche 1B Advances, the "Tranche 1 Advances"); (iv) subject to us achieving certain performance milestones and, beginning upon the earlier of (A) the date on which all amounts available to be drawn under the Tranche 1C Advances have been drawn and (B) the Tranche 1C Expiration Date, on or prior to June 30, 2024, term loan advances in an aggregate principal amount of $15.0 million (the "Tranche 2 Advances"); and (v) subject to approval by the Lenders' respective investment committees in its discretion, on or prior to March 31, 2025, term loan advances in an aggregate principal amount of up to $100.0 million (the "Tranche 3 Advances"). With the exception of the first $15.0 million tranche available on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at the Company's election, subject to applicable conditions to draw.

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 $600.0 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, 2022 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 (expense), net in the Company's consolidated statements of operations. During the year ended December 31, 2022, interest expense included $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, 2022
Principal amount	$ 15,000
End of the term charge	1,042
Less: unamortized issuance discount	(274)
Less: unamortized issuance costs	(113)
Less: unamortized end of term charge	(952)
Net carrying amount	14,702
Less: current maturities	-
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 14,702

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

11. 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, 2022 and December 31, 2021, no cash dividends have been declared or paid.

12. Stock-Based Compensation

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, 2022, 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 46,738,794 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, effective as of January 1, 2022, the number of shares initially available for issuance was increased by 8,033,850 shares of common stock. Shares that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards. As of December 31, 2022, 32,837,138 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, 2021 to December 31, 2022:

	Number of Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	26,687,620		$ 6.85	4.85	$ 74,525
Granted	13,186,659	(1)	4.93	—	—
Exercised	(938,913)		2.47	—	—
Cancelled or forfeited	(4,054,762)		9.15	—	—
Outstanding as of December 31, 2022	34,880,604	(2)	$ 5.98	5.71	$ 10,647
Options exercisable as of December 31, 2022	16,006,889		$ 4.99	3.51	$ 10,510

(1)Includes (a) 11,446,193 stock options that will vest over a four-year service period, (b) 754,910 stock options that will vest immediately upon the satisfaction of specified performance-based vesting conditions which became probable of achievement in December 2022, (c) 563,959 stock options that partially vest on date of grant, then over a three-year service period and upon the satisfaction of specified performance-based vesting conditions, which were achieved during the year ended December 31, 2022, (d) 37,597 stock options that vest upon the satisfaction of specified performance-based vesting conditions, which were not achieved, and (e) 384,000 stock options that will vest on the one-year anniversary of the date of grant.

(2)The 18,873,715 outstanding unvested stock options includes (a) 15,882,029 that will continue to vest over a one to four-year service period, (b) 1,617,399 that will continue to vest over a three to four-year service period and upon the satisfaction of specified performance-based vesting conditions, (c) 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, (d) 673,534 stock options that will vest immediately upon the satisfaction of specified performance-based vesting conditions, which are considered probable of achievement, (e) 216,756 stock options that will continue to vest over a three-year service period and upon the satisfaction of specified performance-based vesting conditions, which were achieved during the year ended December 31, 2022, and (f) 384,000 stock options that will vest on the one-year anniversary of the date of grant.

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, 2022 and 2021, the assumptions used in the Black-Scholes option pricing model were as follows:

	Years Ended December 31,	
	2022	2021
Weighted average expected term in years	5.89	4.16
Weighted average expected stock price volatility	71.7%	80.0%
Risk-free interest rate	1.46% - 4.31%	(0.76)%-1.33%
Expected dividend yield	0%	0%

For the years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of $37.1 million and $41.3 million, respectively.

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock-based awards was $71.6 million, which is expected to be recognized over a weighted average period of 1.85 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, 2022, 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, 2022, 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, 2021 to December 31, 2022:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	7,046,496	6.64	14.01	$ 6,961
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled or forfeited	(124,667)	6.63	—	—
Outstanding as of December 31, 2022	6,921,829	$ 6.64	13.01	$ —
Options exercisable as of December 31, 2022	5,983,060	$ 6.64	13.01	

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, 2022. Thus, the Company did not use the Black Scholes option pricing model to value any new options grants during the year ended December 31, 2022. During the year ended December 31, 2021, the assumptions used in the Black-Scholes option pricing model were as follows:

	Year Ended December 31, 2021
Weighted average expected term in years	8.00
Weighted average expected stock price volatility	70.0%
Risk-free interest rate	(0.70)%-(0.65)%
Expected dividend yield	0%

For the years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of $4.5 million and $21.1 million, respectively.

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock-based awards was $3.1 million which is expected to be recognized over a weighted average period of 0.5 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, 2022 and 2021, the Company recorded share-based compensation expense of $0.7 million and $0.9 million, respectively, in relation to subsidiary EIPs. As of December 31, 2022, there was $0.6 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 1.4 years. As of December 31, 2022, the unrecognized stock-based compensation expense from EIP's awards with liquidity-based performance vesting conditions issued to employees and non-employee directors was approximately $7.3 million, which will be recognized in future periods if and when attainment of the performance criteria becomes probable.

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, 2022, which includes expense related to stock options and restricted stock awards (in thousands):

	Year Ended December 31, 2022			
	atai ESOP	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

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2021, which includes expense related to stock options and restricted stock awards (in thousands):

	Year Ended December 31, 2021			
	atai ESOP	atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ 18,676	$ —	$ 662	$ 19,339
General and administrative	22,667	21,102	255	$ 44,023
Total share based compensation expense	$ 41,343	$ 21,102	$ 917	$ 63,362

13. Income Taxes

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

	Year Ended December 31,	
	2022	2021
Germany	$ (55,845)	$ (89,061)
International	(79,337)	(47,540)
Total loss before income taxes and loss from equity method investments	$ (135,182)	$ (136,601)

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

	Year Ended December 31,	
	2022	2021
Current income tax provision (benefit):		
Germany	$ —	$ —
International	1,155	1,117
Total current income tax provision:	$ 1,155	$ 1,117
Deferred income tax provision (benefit):		
Germany	$ —	$ —
International	5,074	(5,106)
Total deferred income tax provision:	5,074	(5,106)
Total income tax provision:	$ 6,229	$ (3,989)

The international current tax provision for December 31, 2022 and 2021 is primarily comprised of corporate income taxes incurred in the United States, United Kingdom and Australia.

A reconciliation of the statutory income tax rate to the Company's effective income tax rate for continuing operations is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Loss before income taxes:		
Germany	$ (55,845)	$ (89,061)
International	(79,337)	(47,540)
Total loss before income taxes:	(135,182)	(136,601)
German statutory rate	30.18%	30.18%
Expected income tax expense (benefit)	(40,791)	(41,220)
US state income taxes, net of US federal tax benefit	$ (6,509)	$ 132
International tax rate differential	7,276	4,222
IPR&D charges and acquisition adjustments	—	3,251
Effect of Australian R&D tax credit incentives	(338)	(3)
Fair value adjustments	(109)	2,934
Effect of consolidation and deconsolidation of subsidiaries	(1,394)	—
Effect of statutory to US GAAP accounting adjustments	98	(10,409)
Compensation Expenses not deductible under IRC Section 162(m)	411	1,690
Expenses not deductible for tax purposes	(324)	612
Effect of share-based compensation expense	216	192
Other	758	(657)
Change in German and International valuation allowance	46,935	35,267
Total income tax expense	$ 6,229	$ (3,989)
Effective income tax rate:	-4.61%	2.92%

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, 2022 and 2021 was 30.18% (inclusive a corporate income tax rate of 15.83% and trade tax rate of 14.35%). The weighted-average United States corporate income tax rate for year ended December 31, 2022 and 2021 was 21.00%. The weighted-average Australia corporate income tax rate for the year ended December 31, 2022 and 2021 was 27.50%. The weighted-average United Kingdom corporate income tax rate for the year ended December 31, 2022 and 2021 was 19.00%. The Singapore corporate income tax rate for the year ended December 31, 2022 was 17.0%.

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 are provided for the effects of temporary differences between the amounts of assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax purposes.

Significant components of deferred tax assets and deferred tax liabilities consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
German tax loss carryforward	$ 45,560	$ 31,149
International tax loss carryforward	10,585	8,618
Fixed and Intangible assets	-	66
Share compensation	31,078	17,231
Capitalized research and experimentation expenses	11,975	-
Other deductible timing differences	1,864	829
Total deferred tax assets, gross	101,062	57,893
Valuation allowance	(95,678)	(49,442)
Total deferred tax assets, net	$ 5,384	$ 8,451
Deferred tax liabilities:		
Fixed and intangible assets	$ (908)	$ (17)
Unrealized foreign exchange	$ (4,472)	$ (3,326)
Outside basis differences in equity and other investments	(4)	(2)
Total deferred tax liabilities	(5,384)	(3,345)
Total deferred tax asset	$ —	$ 5,106

The valuation allowance provided against net deferred tax assets as of December 31, 2022 and 2021 was $95.7 million and $49.4 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 judgement 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 judgement 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 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.

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.

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, 2022 and 2021 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,	
	2022	2021
Germany tax losses	$ 150,991	$ 103,232
International tax losses	41,908	31,875
Total	$ 192,899	$ 135,107

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 2018 through 2021 tax returns are currently open to audit and have not been subject to audit in any prior year by any tax authority.

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, 2022 and 2021, the Company had no unrecognized tax benefits.

14. 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,	
	2022	2021
Numerator:		
Net loss	$ (157,417)	$ (174,244)
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(5,032)	(6,436)
Net loss attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (152,385)	$ (167,808)
Denominator:		
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. Stockholders - basic and diluted	155,719,585	138,265,859
Net loss per share attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (0.98)	$ (1.21)

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,	
	2022	2021
Options to purchase common stock	34,880,604	26,687,820
HSOP options to purchase common stock	6,921,829	7,179,248
2018 Convertible Promissory Notes - Related Parties (Note 10)	6,201,824	10,521,824
	48,004,257	44,388,892

The remaining 2018 Convertible Notes would be issuable upon the exercise of conversion rights of convertible note holders for 387,614 shares of common stock of ATAI Life Sciences AG, respectively. Upon conversion, it is expected that the remaining 2018 Convertible Notes 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 Note 10 for additional discussion.

15. 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.

Leases

In May 2022 the Company entered into a five year lease arrangement that has not yet commenced. The Company expects the lease to commence during the first half of 2023. This lease will require lease payments over the term of approximately $1.8 million.

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.

16. 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 year ended December 31, 2022, there were no additional milestones achieved under the Otsuka Agreement. For the year ended December 31, 2021, there were no additional milestones achieved under the Otsuka Agreement, except for the upfront transfer of the license. During the year ended December 31, 2021, the Company satisfied the performance obligation related to the license upon delivery of the license and recognized the amount of $19.7 million allocated to the license as license revenue. Additionally, the Company recognized revenues of $0.2 million and $0.6 million related to certain research and development services during the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, the remaining balance of deferred revenue related to the Otsuka Agreement was immaterial.

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, 2022 and 2021, 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, 2022 and 2021, 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 research & 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 share was also expensed as research & development expense during the year ended December 31, 2022. During the years ended December 31, 2022 and 2021, the Company recognized $0.4 million and $0, respectively, of in-process research & development expense in connection with the SPA and the License Agreement.

During the years ended December 31, 2022 and 2021, Kures made no material payments in connection with the Columbia agreement.

Accelerate License Agreement

On April 27, 2021, Psyber entered into a license arrangement with Accelerate Technologies Pte. Ltd. (“Accelerate”), whereby Accelerate grants Psyber non-exclusive rights to license and use the technology to commercialize of Psyber’s BCI-enabled companion digital therapeutics in United States of America, Singapore, Member Countries of the European Union, Canada, Australia and New Zealand as a potential treatment for mental health and behavior change, such as substance use disorders including opioid use disorder, mood and anxiety disorders including post-traumatic stress disorder, and treatment-resistant depression.

During the years ended December 31, 2022 and 2021, Psyber made no material payments pursuant to the Accelerate License agreement.

Dalriada License Agreement

On December 10, 2021, Invyxis, Inc. ("Invyxis"), a wholly owned subsidiary of the Company, entered into an exclusive services and license agreement (the "Invyxis ESLA") with Dalriada Drug Discovery Inc. ("Dalriada"). Under the Invyxis ESLA, 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 addition, Invyxis will pay Dalriada success milestone payments and low single digit royalty payments based on net product sales. Invyxis has the right, but not the obligation, to settle future royalty payments based on net product sales with the Company's common stock. Invyxis 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 Invyxis ESLA, 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, 2022, the Company recorded $2.8 million as research and development expense. The Company did not record a material amount of research & development expense for the year ended December 31, 2021. During the years ended December 31, 2022 and 2021, Invyxis made no other service fee payments to Dalriada.

17. 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 18.0% of the outstanding common stock in the Company as of December 31, 2022 and December 31, 2021, respectively. Galaxy is a NYC-based multi-strategy investment firm that owns 6.5% and 6.7% of the outstanding common stock in the Company as of December 31, 2022 and December 31, 2021, respectively.

Convertible Note Agreements with Perception

In March 2020, Perception entered into the Perception Note Purchase Agreement with the Company and other investors, including related parties, which provided for the issuance of convertible notes of up to $3.9 million, among which Perception issued convertible notes in the aggregate principal amount of $3.3 million to the Company and $0.3 million to Sonia Weiss Pick and Family, and $0.3 million to other investors. In addition, in December 2020, Perception entered into the Perception December 2020 Convertible Note Agreement with the Company and other investors, including related parties, which provided for the issuance of convertible notes of up to $12.0 million in two tranches. Under the First Tranche Funding of $7.0 million, Perception issued an aggregate principal amount of $5.8 million to the Company and $0.4 million to other investors as of December 31, 2020 and $0.2 million to Apeiron, $0.5 million to Sonia Weiss Pick and Family, and $0.1 million to other investors in January 2021. Under the Second Tranche Funding of $5.0 million, Perception issued an aggregate of $4.2 million to the Company, $0.2 million to Apeiron, $0.3 million to Sonia Weiss Pick and Family, and $0.4 million to other investors.

On June 10, 2021, the Company received $20.0 million pursuant to the Otsuka Agreement. Upon receipt of the proceeds, the Perception Convertible Notes automatically converted into Series A preferred stock pursuant to their original terms. Sonia Weiss Pick and Family and Aperion received 440,415 shares and 27,809 shares of Perception Series A preferred stock, respectively, upon conversion of the Perception Convertible Notes. The conversion of the Perception December 2020 Notes was accounted for an extinguishment. The March 2020 Notes were accounted for as a conversion. These transactions are further described in Note 10.

Common Stock

Since 2018, the Company engaged SMC as the underwriting bank to provide banking, advisory services and securities-related technical support of cash and non-cash capital increase transactions. In connection with the issuance of common stock in November 2020, the Company paid SMC an aggregate amount of $4.5 million of advisory fees, of which approximately $3.7 million was paid to Apeiron by SMC during the first quarter of 2021.

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, in connection with the Company's issuance of 13,419,360 shares of common stock, at a price of €9.69 or $11.71 per share, the Company issued common shares to Apeiron for a total purchase price of $14.5 million, and issued common shares to Presight II, L.P. for a total purchase price of $13.9 million (See Note 11). Apeiron is the co-managing member of the general partner of Presight II, L.P.

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. The Consulting Agreement expires on March 31, 2024.

As a result of the Consulting Agreement, for the years ended December 31 2022, and 2021, the Company recorded $0.7 million and $0.6 million, respectively, of stock-based compensation included in general and administrative expense in its consolidated statement of operations.

For the year ended December 31, 2022, the Company recorded $0.6 million of stock-based compensation included in general and administrative expense in its consolidated statement of operations related to Mr. Angermayer's service as Chairman of the supervisory board. For the year ended December 31, 2021, the Company recorded an immaterial amount of general and administrative expense in its consolidated statement of operations related to Mr. Angermayer's service as Chairman of the supervisory board.

18. 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 of related compensation expense for the year ended December 31, 2022. The Company recognized an immaterial amount of compensation expense for the year ended December 31, 2021.

19. Subsequent Events

Loan to IntelGenx

In January 2023, the Company loaned IntelGenx $3.0 million pursuant to the IntelGenx Loan Agreement. See Note 6 for additional discussion.

Reorganization

In February 2023, the Company announced a plan to simplify its organizational design, which included a reduction in force of approximately 30% of the Company's global workforce. The reduction in force is expected to be substantially completed by March 31, 2023.

Lease Commencement

In February 2023, the Company commenced a new lease in Berlin, Germany. This lease will require monthly lease payments over the five year term of approximately $1.8 million.

Hercules Term Loan Amendment

In March 2023, the Company executed an amendment to the Hercules Loan Agreement. Pursuant to the amendment, the Tranche 1B Expiration Date is May 1, 2023.

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, 2022. 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, 2022 at the reasonable assurance level.

Material Weaknesses Previously Identified and Remediated

As previously disclosed, our management identified deficiencies in our internal control over financial reporting that constituted material weaknesses as of December 31, 2021. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that were previously identified were related to the design of internal controls as follows: (1) the lack of a sufficient number of trained professionals with the expertise to design, implement and execute a formal risk assessment process and formal accounting policies, procedures and controls over accounting and financial reporting to ensure the timely recording, review, and reconciliation of financial transactions while maintaining a segregation of duties; (2) the lack of formal processes and controls specific to the identification and recording of expense transactions, including stock-based compensation, completely and accurately, and in the appropriate period; and (3) the lack of a sufficient number of trained professionals with the appropriate U.S. GAAP technical expertise to identify, evaluate and account for complex transactions and review valuation reports prepared by external specialists. As a result, we did not design and maintain formal accounting policies, processes and controls related to complex transactions necessary for an effective financial reporting process.

Remediation of Previously Identified Material Weaknesses

Subsequent to the identification of the material weaknesses, management implemented our previously disclosed remediation plan designed to remediate the material weaknesses and to enhance our overall control environment. Our remediation plan included, but was not limited to, the following measures:

- Engaged consultants to assist management in designing and implementing a formal risk assessment process.
- Formalized our accounting and financial reporting policies and the related procedures and designed and implemented controls over the timely recording, review, and reconciliation of financial transactions, including expense and stock-based compensation transactions.
- Hired additional qualified accounting personnel and implemented accounting systems to support our policies, procedures and controls, while maintaining segregation of duties amongst accounting personnel.
- Designed and implemented controls over the recording and review of technical accounting matters, application of new accounting standards, tax matters, and valuations, and engaged third parties subject to our oversight and review, as needed.

Management has completed its documentation, testing and evaluation of the enhanced controls and determined that, as of December 31, 2022, our controls have been appropriately designed and implemented, and have operated effectively for a sufficient period of time to conclude that these previously identified material weaknesses have been remediated.

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, 2022, 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, 2022.

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, 2022, we finalized the implementation and operation of our internal controls over financial reporting to remediate the previously identified material weaknesses, as described above. Except as discussed above, 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, 2022 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, 2022.

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 2022.

Information About Our Directors & 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	36	Co-Founder and Chief Executive Officer	Same
Srinivas Rao, Ph.D.	54	Co-Founder and Chief Scientific Officer	Same
Rolando Gutiérrez-Esteinou, M.D.	62	Chief Medical Officer	Same
Stephen Bardin	33	Chief Financial Officer	Same
Sahil Kirpekar	38	Chief Business Officer	Same
Christian Angermayer	46	Founder and Chairman	Founder of Apeiron Investment Group
Michael Auerbach	47	Supervisory Director	Founder of Subversive Capital
Jason Camm	34	Supervisory Director	Managing Director and Chief Medical Officer at Thiel Capital
Sabrina Martucci Johnson	56	Supervisory Director	Founder and Chief Executive Officer of Daré Bioscience, Inc.
Amir Kalali, M.D.	57	Supervisory Director	Professor of Psychiatry at the University of California San Diego
Andrea Heslin Smiley	55	Supervisory Director	President and Chief Executive Officer of VMS BioMarketing

Item 11. Executive Compensation.

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, 2022.

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 2023 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

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 2023 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

Item 14. Principal Accountant Fees and Services.

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, 2022.

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.

		Incorporated by Reference				
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed/Furnished Herewith**
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					*
10.28†	Amendment to Series A Preferred Stock Purchase Agreement, dated as of May 25, 2021, by and among ATAI Life Sciences AG and FSV7, Inc.					*
10.29†	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.					*
10.30†	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.					*
21.1	List of Subsidiaries					*
23.1	Consent of Deloitte & Touche LLP, an independent registered public accounting firm					*
23.2	Consent of PricewaterhouseCoopers 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	**
99.1^	Separate Consolidated Financial Statements of COMPASS Pathways plc, as of December 31, 2022 and 2021 and for each of the three years ended December 31, 2022, 2021 and 2020, filed pursuant to Regulation S-X Rule 3-09.	*
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document	*
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.
** Furnished herewith.
^ The audited consolidated financial statements as of and for the years ended December 31, 2022 and 2021 and related notes thereto of COMPASS Pathways plc and its subsidiaries ("COMPASS"), prepared by COMPASS and audited by its independent registered public accounting firm, are included as Exhibit 99.1 to this Form 10-K and are incorporated by reference herein. We are required to include the COMPASS financial statements in this Form 10-K due to COMPASS meeting certain tests of significance under Rule 3-09 of Regulation S-X. The management of COMPASS is solely responsible for the form and content of the COMPASS financial statements.
# 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 24, 2023

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 24, 2023
/s/ Stephen Bardin Stephen Bardin	Chief Financial Officer and Managing Director (Principal Financial Officer and Principal Accounting Officer)	March 24, 2023
/s/ Christian Angermayer Christian Angermayer	Chairman of the Supervisory Board	March 24, 2023
/s/ Michael Auerbach Michael Auerbach	Supervisory Director	March 24, 2023
/s/ Jason Camm Jason Camm	Supervisory Director	March 24, 2023
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Supervisory Director	March 24, 2023
/s/ Amir Kalali Amir Kalali	Supervisory Director	March 24, 2023
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Supervisory Director	March 24, 2023

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.

FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This **First Amendment to Loan and Security Agreement** (this "**Amendment**") is dated as of March 13, 2023 and is entered into by and among ATAI LIFE SCIENCES N.V., a public limited liability company (naamloze vennootschap) incorporated under the laws of the Netherlands, having its corporate seat (statutaire zetel) in Amsterdam, the Netherlands, its registered office at Wallstraße 16, 10179 Berlin, Federal Republic of Germany, and registered with the trade register of the Chamber of Commerce (handelsregister van de Kamer van Koophandel) under number 80299776 ("**Parent**"), ATAI LIFE SCIENCES AG, a stock corporation (Aktiengesellschaft) incorporated under the laws of Germany and registered with the commercial register of the local court of Munich under HRB 239201, with business address at Wallstraße 16, 10179 Berlin ("**ATAI Germany**", and together with Parent, ATAI Germany and each other Person party to the Loan Agreement as a borrower from time to time, individually or collectively, as the context may require, "**Borrower**"), ATAI LIFE SCIENCES US, INC., a Delaware corporation ("**ATAI US**"), INTROSPECT DIGITAL THERAPEUTICS, INC., a Delaware corporation ("**IntroSpect**"), Viridia Life Sciences, Inc., a Delaware corporation ("**Viridia**"), EmpathBio, Inc., a Delaware corporation ("**Empath**"), Invyxis, Inc., a Delaware corporation ("**Invyxis**"), and Revixia Life Sciences, Inc., a Delaware corporation ("**Revixia**", and together with ATAI US, IntroSpect, Viridia, Empath, Invyxis, and any other Person party to the Loan Agreement from time to time as a guarantor, collectively, the "**Guarantors**" and each a "**Guarantor**"), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively referred to as the "**Lenders**" and each a "**Lender**") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, "**Agent**"). Capitalized terms used herein without definition shall have the same meanings given them in the Loan Agreement (as defined below).

Recitals

A.Borrower, Guarantors, Agent and Lenders have entered into that certain Loan and Security Agreement dated as of August 9, 2022, among Borrower, Guarantors, Agent and Lenders (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"), pursuant to which Lenders have agreed to extend and make available to Borrower certain advances of money.

B.In accordance with Section 11.3 of the Loan Agreement, Borrower has requested that Agent and Lenders agree to amend certain provisions of the Loan Agreement.

C.Agent and Lenders have agreed to so amend the Loan Agreement upon the terms and conditions more fully set forth herein.

Agreement

NOW, THEREFORE, in consideration of the foregoing Recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1.Amendments.

1.1 The Loan Agreement is hereby amended as follows:

(a) Section 2.2(a)(i). Section 2.2(a)(i) is hereby amended and restated as follows:

"(i) *Tranche 1*. Subject to the terms and conditions of this Agreement and the proviso hereto, (A) on the Closing Date, Lenders shall severally (and not jointly) make, and Borrower agrees to draw, a Term Loan Advance in an aggregate principal amount equal to Fifteen Million Dollars ($15,000,000) (such Term Loan Advance, the "Tranche 1A Advance"), (B) at any time after the Closing Date but on or prior to May 1, 2023 (the "Tranche 1B Expiration Date"), Borrower may request and Lenders shall severally (and not jointly) make additional Term Loan Advances in an aggregate principal amount not to exceed Twenty Million Dollars ($20,000,000) (such Term Loan Advances, the "Tranche 1B Advances") in minimum increments of Five Million Dollars ($5,000,000) (or if less than Five Million Dollars ($5,000,000) the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(i)(B)) and (C) at any time beginning upon the earlier of (i) the Tranche 1B Expiration Date and (ii) the date on which all amounts available to be drawn pursuant to Section 2.2(a)(i)(B) have been drawn and on or prior to December 15, 2023 (the "Tranche 1C Expiration Date"), Borrower may request and Lenders shall severally (and not jointly) make additional Term Loan Advances in an aggregate principal amount not to exceed Twenty Five Million Dollars ($25,000,000) (such Term Loan Advances, the "Tranche 1C Advances") in minimum increments of Five Million Dollars ($5,000,000) (or if less than Five Million Dollars ($5,000,000) the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(i)(C)); provided the aggregate Term Loan Advances made by any Lender pursuant to clause (A), (B) and (C) above shall not exceed its respective Tranche 1 Commitment and the aggregate principal amount of the Term Loan Advances made pursuant to this Section 2.2(a)(i) shall not exceed Sixty Million Dollars ($60,000,000)."

1.2 Each reference in the Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

2.Loan Parties' Representations And Warranties. Each Loan Party represents and warrants that:

2.1 Immediately upon giving effect to this Amendment, (i) the representations and warranties contained in the Loan Documents are true and correct in all material respects except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date and (ii) no default or Event of Default has occurred and is continuing with respect to which such Loan Party has not been notified in writing by Agent or Lenders.

2.2 Each of the Loan Parties has the corporate power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment.

2.3 The execution and delivery by the Loan Parties of this Amendment and the performance by each of the Loan Parties of its obligations under the Loan Agreement, as amended

by this Amendment, have been duly authorized by all necessary corporate action on the part of such Loan Party.

2.4 This Amendment has been duly executed and delivered by each Loan Party and is the binding obligation of such Loan Party, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

2.5 As of the date hereof, it has no defenses against the obligations to pay any amounts under the Secured Obligations. Each Loan Party acknowledges that each of Agent and the Lenders has, as of the date hereof, acted in good faith and has conducted in a commercially reasonable manner its relationships with the Loan Parties in connection with this Amendment and in connection with the Loan Documents.

Each Loan Party understands and acknowledges that each of Agent and the Lenders is entering into this Amendment in reliance upon, and in partial consideration for, the above representations and warranties, and agrees that such reliance is reasonable and appropriate.

3. Limitation. The amendments set forth in this Amendment shall be limited precisely as written and shall not be deemed (a) to be a waiver or modification of any other term or condition of the Loan Agreement or of any other instrument or agreement referred to therein or to prejudice any right or remedy which Agent and/or Lenders may now have or may have in the future under or in connection with the Loan Agreement (as amended hereby) or any instrument or agreement referred to therein; or (b) to be a consent to any future amendment or modification or waiver to any instrument or agreement the execution and delivery of which is consented to hereby. Except as expressly amended hereby, the Loan Agreement shall continue in full force and effect.

4. Effectiveness. This Amendment shall become effective upon the satisfaction of all the following conditions precedent (such date of satisfaction of all such conditions precedent, the "**First Amendment Closing Date**"):

4.1 Amendment. Borrower, Guarantors, Agent and Lenders shall have duly executed and delivered this Amendment to the Lenders.

4.2 Payment of Lenders' Expenses. The Loan Parties shall have paid all reasonable Lenders' expenses (including all reasonable attorneys' fees and reasonable expenses) incurred through the date of this Amendment for the documentation and negotiation of this Amendment, in each case, to the extent invoiced on or prior to the First Amendment Closing Date.

5. Release. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law

and in equity, which such Loan Party, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time prior to the execution of this Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Each Loan Party understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Each Loan Party agrees that no fact, event, circumstance, evidence or transaction existing prior to the execution of this Amendment which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Each Loan Party waives the provisions of California Civil Code section 1542, which states:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

6.Counterparts. This Amendment may be signed in any number of counterparts, and by different parties hereto in separate counterparts, with the same effect as if the signatures to each such counterpart were upon a single instrument. All counterparts shall be deemed an original of this Amendment. This Amendment may be executed by facsimile, portable document format (.pdf) or similar technology signature, and such signature shall constitute an original for all purposes.

7.Incorporation By Reference. The provisions of Section 11 of the Loan Agreement shall be deemed incorporated herein by reference, *mutatis mutandis*.

8.Reaffirmation. By executing and delivering a counterpart hereof, (i) each Loan Party hereby agrees that all Advances incurred by such Loan Party shall be secured by the Collateral pursuant to the applicable Loan Documents in accordance with the terms and provisions thereof and (ii) each Loan Party hereby (A) agrees that, notwithstanding the effectiveness of this Amendment, after giving effect to this Amendment, the Loan Documents continue to be in full force and effect, (B) agrees that all of the Liens and security interests created and arising under the Loan Documents remain in full force and effect on a continuous basis, and the perfected status and priority of each such Lien and security interest continues in full force and effect on a continuous basis, unimpaired, uninterrupted and undischarged, as collateral security for its obligations, liabilities and indebtedness under the Loan Agreement to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Amendment) and (C) affirms and confirms all of its obligations, liabilities and indebtedness under the Loan Agreement and each other Loan Document, in each case after giving effect to this Amendment, including the pledge of and/or grant of a security interest in its assets as Collateral pursuant to the Loan Documents to secure such Secured Obligations, all as provided in the Loan Documents, and acknowledges and agrees that such obligations, liabilities, guarantee, pledge and grant continue in full force and effect in respect of, and to secure, such Secured Obligations under the Loan Agreement and the other Loan Documents, in each case, to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Amendment).

[Signature Page Follows]

In Witness Whereof, the parties have duly authorized and caused this Amendment to be executed as of the date first written above.

BORROWER:

ATAI LIFE SCIENCES N.V.

Signature: /s/ Stephen Bardin

Print Name: Stephen Bardin

Title: Chief Financial Officer

ATAI LIFE SCIENCES AG

Signature: /s/ Stephen Bardin

Print Name: Stephen Bardin

Title: Chief Financial Officer

[Signature Page – First Amendment to LSA]

GUARANTORS:

ATAI LIFE SCIENCES US, INC.

Signature: /s/ Stephen Bardin

Print Name: Stephen Bardin

Title: Treasurer

INTROSPECT DIGITAL THERAPEUTICS, INC.,
VIRIDIA LIFE SCIENCES, INC.,
EMPATHBIO, INC., and
REVIXIA LIFE SCIENCES, INC.

Signature: /s/ Stephen Bardin

Print Name: Stephen Bardin

Title: Treasurer

INVYXIS, INC.

Signature: /s/ Stephen Bardin

Print Name: Stephen Bardin

Title: Treasurer

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: CFO

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: CFO

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

Exhibit 10.28

[***] Certain information in this document has been omitted from this exhibit because (i) the Company customarily and actually treats such information as private or confidential and (ii) the omitted information is not material.

AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT

THIS AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT (this "**Amendment**") is entered into as of May 25, 2021 (the "**Effective Date**"), by and among ATAI LIFE SCIENCES AG, a German corporation ("**ATAI**"), and FSV7, INC., a Delaware corporation now named RECOGNIFY LIFE SCIENCES, INC. (the "**Company**" and referred to, collectively with ATAI, as the "**Parties**").

W I T N E S S E T H:

A. The Parties have entered into that certain SERIES A PREFERRED STOCK PURCHASE AGREEMENT dated as of November 6, 2020 (the "**SPA**").

B. The Company needs additional funding for its phase 2a Study and ATAI agrees to provide $[***] as a pre-payment on Milestone 2 ("**Pre-Payment**").

C. ATAI and the Company desire to amend the SPA in connection with the Pre- Payment.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

SECTION 1. Defined Terms. Capitalized terms used herein (including in the preamble and recitals above) but not otherwise defined herein shall have the respective meanings ascribed to such terms in the SPA.

SECTION 2. Pre-Payment of a Portion of Milestone 2. The Parties agree that, otherwise pursuant to the terms and subject to the conditions set forth in the SPA, ATAI shall pay the Company $[***] as soon as practicable following the signing this Amendment and that the Company shall release [***] shares of Series A Preferred Stock to ATAI.

SECTION 3. Amendments. The Parties agree that the SPA shall be amended as follows:

(1) Section 1.3(a)(ii) shall be amended to read as follows: "[***] shares of Series A Preferred Stock at the Purchase Price on the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) that the events specified

under “Milestone 2” in Exhibit I attached to this Agreement have occurred (“**Milestone 2**”); and” and

(2)The last sentence of Milestone 2 in **Exhibit I** of the SPA shall be amended to read as follows: “At the completion of a positive Stage 1, upon the certification by the Board pursuant to Section 1.3(a)(ii) of the Agreement, ATAI shall pay to the Company
$[***]. This funding will be used to fund Stage 2.”

SECTION 4. Use of Proceeds. The Parties agree that, notwithstanding anything set forth in Section 1.5 of the SPA to the contrary, the proceeds from the Pre-Payment covered by this Amendment shall be used to fund the first phase 2a Study.

SECTION 5. Counterparts. This Amendment may be executed in any number of counterparts and by the different parties hereto on separate counterparts and each such counterpart shall be deemed to be an original, but all such counterparts shall together constitute but one and the same Amendment. Receipt by facsimile or other electronic transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.hellosign.com) of any executed signature page to this Amendment shall constitute effective delivery of such signature page.

SECTION 6. SPA. Other than as specifically set forth herein, the SPA shall remain in full force and effect.

SECTION 7. Miscellaneous. Sections 6.2, 6.3, 6.5 through 6.13 and 6.15 of the SPA (or any successor provisions thereto) shall apply to this Amendment *mutatis mutandis*.

[Signature Pages Follow]

Each of the undersigned has caused the Amendment to be duly executed and delivered as of the date first above written.

RECOGNIFY LIFE SCIENCES, INC.

By: /s/ Matthew P. Pando
Name: Matthew P. Pando
Title: Chief Executive Officer

ATAI LIFE SCIENCES AG

By: /s/ Florian Brand
Name: Florian Brand
Title: Chief Executive Officer

Exhibit 10.29

[***] Certain information in this document has been omitted from this exhibit because (i) the Company customarily and actually treats such information as private or confidential and (ii) the omitted information is not material.

SECOND AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT

THIS SECOND AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT (this "**Second Amendment**") is entered into as of September 17, 2021 (the "**Effective Date**"), by and among ATAI LIFE SCIENCES AG, a German corporation ("**ATAI**"), and RECOGNIFY LIFE SCIENCES, INC., a Delaware corporation, formerly known as FSV7, Inc. (the "**Company**" and referred to, collectively with ATAI, as the "**Parties**").

W I T N E S S E T H:

A. The Parties and others have entered into that certain SERIES A PREFERRED STOCK PURCHASE AGREEMENT dated as of November 6, 2020 (the "**SPA**").

B. The Parties have entered into that certain AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT dated as of May 27, 2021 (the "**First Amendment**") whereby ATAI provided additional funding to the Company for its phase 2a Study in the amount of $[***] as a pre-payment on Milestone 2 ("**First Pre-Payment**").

C. The Company has advised ATAI that it needs additional funding for its initial phase 2a Study (Stage 1), as well as the preparation of the next phase 2a study (Stage 2), and ATAI has agreed to provide $[***] as a second pre-payment on Milestone 2 ("**Second Pre-Payment**").

D. ATAI and the Company desire to further amend the SPA in connection with the Second Pre-Payment.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

SECTION 1. Defined Terms. Capitalized terms used herein (including in the preamble and recitals above) but not otherwise defined herein shall have the respective meanings ascribed to such terms in the SPA.

SECTION 2. Second Pre-Payment of a Portion of Milestone 2. The Parties agree that, pursuant to the terms and subject to the conditions set forth in the SPA, ATAI shall pay the Company $[***] as soon as practicable following the signing of this Second Amendment and that the Company shall immediately release [***] shares of Series A Preferred Stock to ATAI.

SECTION 3. Amendments. The Parties agree that the SPA shall be amended as follows:

(1)Section 1.3(a)(ii) shall be amended to read as follows: "[***] shares of Series A Preferred Stock at the Purchase Price on the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) that the events specified under "Milestone 2" in Exhibit I attached to this Agreement have occurred ("**Milestone 2**"); and" and

(2)The last sentence of Milestone 2 in **Exhibit I** of the SPA shall be amended to read as follows: "At the completion of a positive Stage 1, upon the certification by the Board pursuant to Section 1.3(a)(ii) of the Agreement, ATAI shall pay to the Company
$[***]. This funding will be used to fund Stage 2."

SECTION 4. Use of Proceeds. The Parties agree that, notwithstanding anything set forth in Section 1.5 of the SPA to the contrary, the proceeds from the Second Pre-Payment covered by this Second Amendment shall be used to fund either the first or the second phase 2a Study.

SECTION 5. Counterparts. This Second Amendment may be executed in any number of counterparts and by the different parties hereto on separate counterparts and each such counterpart shall be deemed to be an original, but all such counterparts shall together constitute but one and the same Second Amendment. Receipt by facsimile or other electronic transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.hellosign.com) of any executed signature page to this Second Amendment shall constitute effective delivery of such signature page.

SECTION 6. SPA. Other than as specifically set forth herein and in the First Amendment, the SPA shall remain in full force and effect.

SECTION 7. Miscellaneous. Sections 6.2, 6.3, 6.5 through 6.13 and 6.15 of the SPA (or any successor provisions thereto) shall apply to this Second Amendment *mutatis mutandis*.

[Signature Page Follows]

Each of the undersigned has caused the Second Amendment to be duly executed and delivered as of the date first above written.

RECOGNIFY LIFE SCIENCES, INC.

By: /s/ Matthew P. Pando
Name: Matthew P. Pando
Title: Chief Executive Officer

ATAI LIFE SCIENCES AG

By: /s/ Florian Brand
Name: Florian Brand
Title: Chief Executive Officer

Exhibit 10.30

[***] Certain information in this document has been omitted from this exhibit because (i) the Company customarily and actually treats such information as private or confidential and (ii) the omitted information is not material.

OMNIBUS AMENDMENT

THIS OMNIBUS AMENDMENT (this "**Amendment**") is entered into as of October 05, 2022, by and among ATAI LIFE SCIENCES AG, a German corporation ("**ATAI**"), RECOGNIFY LIFE SCIENCES, INC., f/k/a FSV7, INC., a Delaware corporation, a Delaware corporation (the "**Company**") and the other persons and entities listed on Exhibit A hereto (the "**Shareholders**" and collectively with ATAI (and ATAI LIFE SCIENCES US, INC., only for purposes of Section 5 below), and the Company, the "**Parties**").

W I T N E S S E T H:

A. The Shareholders, ATAI (or, in the case of the ISA, as defined below, ATAI LIFE SCIENCES US, INC.) and the Company have entered into (i) that certain SERIES A PREFERRED STOCK PURCHASE AGREEMENT (the "**SPA**"), (ii) that certain VOTING AGREEMENT (the "**VA**"), (iii) that certain INVESTORS' RIGHTS AGREEMENT (the "**IRA**"), and (iv) that certain INTERCOMPANY SERVICES AGREEMENT (the "**ISA**"), each dated as of November 6, 2020 (each as amended, restated, amended and restated, supplemented or otherwise modified from time to time, including, without limitation, with respect to the SPA through that certain AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT dated May 27, 2021 ("**Amendment 1**"), and the SECOND AMENDMENT TO SERIES A PREFERRED STOCK PURCHASE AGREEMENT dated September 17, 2021 ("**Amendment 2**"); collectively, the agreements in (i) through (iv), the "**Agreements**").

B. ATAI at the Initial Closing and subsequent Milestone Closings previously funded Milestones 1 and 2 (including through the First Pre-Payment and the Second Pre-Payment (each as defined in Amendment 2)) in an aggregate amount of $[***] in exchange for a total of [***] shares of Series A Preferred Stock (which are no longer subject to the Repurchase Option), with [***] shares remaining as Escrow Shares.

C. The Parties have agreed on a new POC Study design taking into consideration certain Go and No-Go Events (each as defined below) and in connection therewith desire to further amend the SPA to amend Milestone 3 and to determine future funding of the Company by ATAI and the related Milestones based on such Go and No-Go Events.

D. The Parties also desire to amend the Voting Agreement to clarify the composition of the Board of Directors of the Company.

E. Further, the Parties desire to amend the IRA to add certain provisions taking into consideration the public company status of ATAI Life Sciences N.V. ("**ATAI N.V**.") and the impact on its direct and indirect subsidiaries, including the Company.

F. Further, the Company and ATAI desire to amend the ISA to better reflect the services provided by ATAI to its Subsidiaries.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

SECTION 1. Defined Terms. Capitalized terms used herein (including in the preamble and recitals above) but not otherwise defined herein shall have the respective meanings ascribed to such terms in the SPA.

SECTION 2. Amendments to SPA. The parties hereby agree that the SPA Agreement shall be amended as set forth below:

(a)Section 1.3 (a)(iii) of the SPA shall hereby be amended by deleting it in its entirety and replacing it with the following:

> "(iii) Subject to Section 1.3(d) below, (A) [***] shares of Series A Preferred Stock at the Purchase Price on the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) that the events specified under "Milestone 3 First Tranche" in Exhibit I have occurred ("**Milestone 3 First Tranche**"), (B) [***] shares of Series A Preferred Stock at the Purchase Price on the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) that the events specified under "Milestone 3 Second Tranche" in Exhibit I have occurred ("**Milestone 3 Second Tranche**") and (C) [***] shares of Series A Preferred Stock at the Purchase Price on the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) that the events specified under "Milestone 3 Third Tranche" in Exhibit I have occurred ("**Milestone 3 Third Tranche**"; and collectively, with Milestone 3 First Tranche, and Milestone 3 Second Tranche "**Milestone 3**" and together with Milestone 1 and Milestone 2, the "**Milestones**"); provided however, ATAI shall have the right, but not the obligation, to make payment for up to [***] of the Milestone Shares at any time upon notice to the Company, irrespective of the achievement of any Milestone and, upon such payment, the Company shall instruct the Escrow Agent to release to ATAI the corresponding number of Escrow Shares."

(b)Section 1.3 (d) of the SPA shall hereby be amended by deleting it in its entirety and replacing it with the following:

> "(d) If, following achievement of Milestone 3 Second Tranche in full, the Company reasonably determines that additional funding is required for completion of the Proof of Concept (POC) Study, then the Company and ATAI shall negotiate in good faith (including the price per share for the shares to be issued in the Additional Funding (as defined below)) and in accordance with the underlying principles of this Agreement shall make an update to the Initial Clinical Development Plan set forth on Exhibit B hereto (such update, the "**Clinical Development Plan**") and an increase to the budget necessary to complete the POC Study (any such increase, not to exceed $[***] in excess of the $[***] provided for hereunder, the "**Additional Funding**"); and, subject to the Parties agreement with respect to such Additional Funding, the

Company and ATAI shall further amend Milestone 3 (or any tranche thereof) and the corresponding number of Milestone Shares (not to exceed [***] shares of Series A Preferred Stock) funded by ATAI and released from escrow (or as may otherwise be required to be issued), and amend Exhibit I accordingly. For the avoidance of doubt, (i) if the Parties agree that Additional Funding is to be provided, the Company will be deemed to have agreed that the overall funding requirements hereunder (including the POC Study) will require more than a total of $[***] for all purposes hereof, including for purposes of Section 4.15(c) herein; and (ii) the issuance of any additional shares associated with the Additional Funding would be effected without prejudice or detriment to the Second Warrant or the shares of Series A Preferred Stock issued pursuant thereto."

(c)Exhibit I of the SPA shall hereby be amended by deleting the text under "Milestone 3" thereof in its entirety and replacing it with the following:

"Milestone 3:

Milestone 3 First Tranche

ATAI shall pay to the Company $[***] upon the certification by the Board (as confirmed by ATAI, which confirmation not to be unreasonably withheld) of a final Clinical Development Plan, to include go/no-go decisions based on Phase 2 Proof of Concept (POC) Study (the "**POC Study**"), for development of FSV7-007 in cognitive impairment associated with schizophrenia to be further set forth on Exhibit J hereto, the cost of which shall not exceed the maximum estimates per period and phase as set forth on such Exhibit. Unless otherwise agreed by the Board (as confirmed by ATAI, which confirmation is not to be unreasonably withheld), a 3-person independent data monitoring committee (whose members shall be mutually agreeable to ATAI and the Company) (the "**Independent Data Monitoring Committee**") shall, in its sole discretion, recommend based on its expert interpretation of the statistical analytical plan for the adaptive three arm parallel RCT design with two interim analyses, in accordance with the statistical analysis plan set forth on Exhibit C hereto (the "SAP", which SAP shall not be amended or replaced without ATAI's prior written consent) (such recommendation based on such SAP, a "**Recommendation**"), a commitment to stop further development for the relevant arm (each a "**No-Go Event**"). If the Independent Data Monitoring Committee makes a Recommendation that a No-Go Event has occurred, the relevant arm shall be discontinued. For clarity, if the Independent Data Monitoring Committee makes a Recommendation that states that the first interim analysis or the second interim analysis does not result in a No-Go Event for a given arm, such result shall constitute a "**Go-Event**" related to such interim analysis for all purposes hereof.

Milestone 3 Second Tranche

ATAI shall pay to the Company $[***] upon the achievement of least one Go-Event following the Recommendation from the Independent Data Monitoring Committee and the readout of the first interim analysis of the POC Study.

Milestone 3 Third Tranche

ATAI shall pay to the Company $[***] upon (i) the achievement of at least one Go-Event following the recommendation from the Independent Data Monitoring Committee and the readout of the second interim analysis of the POC Study and (ii) the unanimous written certification by the Board. For the avoidance of doubt, if the Board (excluding the board members affiliated with ATAI) agrees that Milestone 3 Third Tranche payment is to be provided, the Company will be deemed to have agreed that the overall funding requirements hereunder (including the POC Study) will require more than a total of $[***] for all purposes hereof, including for purposes of Section 4.15(c) herein; and the issuance of any shares associated with the Milestone 3 Third Tranche would be effected without prejudice or detriment to the Second Warrant or the shares of Series A Preferred Stock issued pursuant thereto.

(d)Exhibit J of the SPA shall hereby be amended by deleting all text under "Stage 3" thereof in its entirety and replacing it with the Exhibit B attached hereto.

SECTION 3. Amendments to the VA. The parties hereby agree that Section 1.2(d) of the VA shall hereby amended by deleting it in its entirety and replacing it with the following:

"(d) One person designated from time to time by the holders of a majority of the outstanding Common Stock and the holders of a majority of the outstanding Preferred Stock, voting as separate classes; provided, however, that from and after such time when ATAI has purchased [***] shares of the Milestone Shares (as defined in the Purchase Agreement), the member of the Board referred to in this Section 1.2(d) shall instead be designated from time to time by the holders of a majority of the outstanding Common Stock (including shares of Common Stock issued or issuable upon conversion of the Preferred Stock) held by the Stockholders, voting together as a single class on an as-converted basis, which seat shall initially be Srinivas Rao;"

SECTION 4. Amendments to the IRA. The parties hereby agree that the IRA shall be amended as set forth below:

(a)Section 3.1 of the IRA shall hereby be amended by deleting it in its entirety and replacing it with the following:

"3.1 Delivery of Financial Statements. The Company shall deliver to each Major Investor:

(a)as soon as practicable, but in any event within thirty (30) days after the end of each fiscal year of the Company (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and a comparison between (x) the

actual amounts as of and for such fiscal year and (y) the comparable amounts for the prior year and as included in the Budget (as defined in Section 3.1(d)) for such year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such year, and (iii) a statement of stockholders' equity as of the end of such year;

(b)as soon as practicable, but in any event within fifteen (15) days after the end of the first three quarters of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c)as soon as practicable, but in any event within five (5) days after the end of each quarter of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(d)as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year, prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company (such budget and business plan that is approved by the Board of Directors (including a majority of the Preferred Directors then seated, the "**Requisite Preferred Director Vote**") is collectively referred to herein as the "**Budget**");

(e)with respect to the financial statements called for in Section 3.1(a), Section 3.1(b) and Section 3.1(d), an instrument executed by the chief financial officer and chief executive officer of the Company certifying that such financial statements were prepared in accordance with GAAP consistently applied with prior practice for earlier periods (except as otherwise set forth in Section 3.1(b) and Section 3.1(d)) and fairly present the financial condition of the Company and its results of operation for the periods specified therein; and

(f)promptly, but in no event more than one Business Day after occurrence of the event triggering the same, (i) information about the formation of any Subsidiary of the Company (including providing a full set of any organizational documents relating to such new Subsidiary), (ii) information about any investment by the Company in any debt or equity security of any other Person (together with any relevant documents evidencing the same), (iii) information about any indebtedness for borrowed money

(including a guarantee of the same or the provision of any security interest in assets of the Company or any Subsidiary thereof for the benefit of any Person other than ATAI or its Subsidiaries other than the Company) incurred by the Company or any Subsidiary thereof (including the relevant documents) and (iv) any material amendment, restatement, supplement or other modification to any of the foregoing;

(g)such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Section 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel;

provided that, if any timeline in the aforementioned subsections (a) through (d) is not met (or not likely to be met) predominantly due to a delay or other failure by ATAI to provide the relevant accounting services under the ISA, the Board shall decide on a reasonable extension of the same.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries."

(b)The IRA shall hereby be amended by adding a new Section 5.9 thereto (and renumbering the existing Section 5.9 as 5.10) reading as follows:

"5.9 Platform Company Status. The Company acknowledges and agrees that it is a Subsidiary of ATAI and as such an indirect subsidiary of ATAI Life Sciences N.V. which is listed on the Nasdaq Global Market and as a result is subject to its rules and regulations as well as applicable US securities laws. While the Company is a Subsidiary of ATAI, it shall therefore adopt relevant policies and procedures as reasonably requested from time to time by ATAI applicable to itself and its other Subsidiaries, including, without limitation, its Code of Conduct, Insider Trading Policy and Regulation FD Policy. In addition, the Company and its Subsidiaries shall maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Further, to the extent necessary to comply with applicable SEC rules, the Company has established disclosure controls and procedures (as defined in 1934 Act Rules 13a-15(e) and 15d-15(e)) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company, including the Subsidiaries, is made known to the certifying officers by others within those entities, particularly during the period in which ATAI N.V.'s most recently filed period

report under the 1934 Act, as the case may be, is being prepared. The Company shall follow, and shall cause its Subsidiaries to follow the authority levels with respect to its officers and employees, as may be established by the Company's Board from time to time, which the Company hereby acknowledges and agrees shall be consistent with the authorization levels established by ATAI for the officers and employees of itself and its other Subsidiaries.

SECTION 5. Amendments to the ISA.

(a)Section 1.2(e) of the ISA shall hereby be amended by deleting it in its entirety and replacing it with the following:

"(e) Human Resources ("HR"). HR services include assistance with recruitment, sourcing and selection of employees, development and management of HR strategy and policies, support management of employee relations, development and deployment of employee rewards and retention programs, coordinate employee redeployment and retirement, management of employee information and analytics, management of employee communications and management of union relations, providing payroll services, participation of employees of the Company and its Subsidiaries in health insurance and other benefits plans generally available to direct and indirect Subsidiaries of ATAI, including (without limitation access to and maintenance of Workiva, Veeva) administration of the same; assistance with HR compliance services;"

(b)Section 1.2 of the ISA shall hereby be amended by adding a new subsection (n) at the end thereof, reading as follows:

"(n) Contract Review, Administration and Management Services. Contract Review, Administration and Management Services includes access to Ironclad or any other contract management and project management software maintained by ATAI for the benefit of itself and its Subsidiaries as well as associated support by ATAI personnel in accessing and uploading documents and otherwise using such software; access to form documents for standard contracts and agreements and associated administrative support by ATAI personnel (which shall not, however, for the avoidance of doubt, include any legal services)."

(c)The Parties further acknowledge and agree that Exhibit A to the Agreement and the relevant Statements of Work (Exhibit B-2 and onwards) will have to be amended to reflect the new and expanded services and agreed to negotiate in good faith to amend the same no later than 60 days following the date hereof on an arms-length basis and consistent with the terms proposed by ATAI for its controlled subsidiaries in general.

SECTION 6. Further Assurances. Each of the parties hereto agrees to execute, acknowledge, seal and deliver, after the date hereof, without additional consideration, such further assurances, instruments and documents, and to take such further actions, as another party may reasonably request in order to fulfill the intent of this agreement and the transactions contemplated hereby.

SECTION 7. Counterparts. This Amendment may be executed in any number of counterparts and by the different parties hereto on separate counterparts and each such counterpart shall be deemed to be an original, but all such counterparts shall together constitute but one and the same Amendment. Receipt by facsimile or other electronic transmission (including pdf or any

electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) of any executed signature page to this Amendment shall constitute effective delivery of such signature page.

SECTION 8. Agreements. Other than as specifically set forth herein, the Agreements shall remain in full force and effect.

SECTION 9. Miscellaneous. Sections 6.2, 6.3, 6.5 through 6.13 and 6.15 of the SPA (or any successor provisions thereto) shall apply to this Amendment *mutatis mutandis*.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

COMPANY:
RECOGNIFY LIFE SCIENCES, INC.

By: /s/ Matthew P. Pando

Name: Matthew P. Pando

Title: Chief Executive Officer

(Recognify Life Sciences, Inc. - Signature page to Series A Omnibus Amendment)

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

ATAI:
ATAI LIFE SCIENCES AG

By: /s/ Florian Brand

Name: Florian Brand

Title: Chief Executive Officer

Only for purposes of Section 5:

ATAI LIFE SCIENCES US, INC.

By: /s/ Florian Brand

Name: Florian Brand

Title: Chief Executive Officer

(Recognify Life Sciences, Inc. - Signature page to Series A Omnibus Amendment)

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

By: /s/ K. Angela Macfarlane

Name: K. Angela Macfarlane

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above

SHAREHOLDER

By: /s/ Matthew Pando

Name: Matthew Pando

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

By: /s/ Eugene de Juan, Jr.

Name: Eugene de Juan, Jr.

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

By: /s/ Gary Walker

Name: Gary Walker

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

IN WITNESS WHEREOF, the parties have executed this Omnibus Agreement as of the date first written above.

SHAREHOLDER:

Donello Family Trust

Name: /s/ John Donello

Name: John Donello

Title: Trustee

EXHIBIT A TO
OMNIBUS AGREEMENT SHAREHOLDERS

ATAI Life Sciences AG

K. Angela, Macfarlane Pando, Matthew
Walker, Gary
de Juan, Jr., Eugene Donello Family
Trust

EXHIBIT B TO
OMNIBUS AGREEMENT

EXHIBIT J TO SPA

Clinical Development Plan

[Omitted]

Exhibit 21.1

Subsidiaries of the Registrant

Name	State or Other Jurisdiction of Incorporation or Organization
DemeRx IB, Inc.	Delaware
DemeRx NB, Inc.	Delaware
GABA Therapeutics, Inc.	Delaware
Invyxis, Inc.	Delaware
TryptageniX, Inc.	Delaware
Kures Inc.	Delaware
Recognify Life Sciences, Inc.	Delaware
Perception Neuroscience Holdings, Inc.	Delaware
Viridia Life Sciences, Inc.	Delaware
EmpathBio, Inc.	Delaware
Revixia Life Sciences, Inc.	Delaware
IntroSpect Digital Therapeutics, Inc.	Delaware
InnarisBio, Inc.	Delaware
EntheogeniX Biosciences, Inc.	Delaware
Psyber, Inc.	Delaware
PsyProtix, Inc.	Delaware
Atai Life Sciences US, Inc.	Delaware
Atai Life Sciences AG	Germany
Atai Life Sciences UK Ltd	England and Wales

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 24, 2023, 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, 2022.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey
March 24, 2023

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-265970) and Form S-8 (No. 333-257482) of ATAI Life Sciences N.V. of our report dated February 28, 2023 relating to the financial statements of COMPASS Pathways plc, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Reading, United Kingdom
March 24, 2023

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 24, 2023

By: /s/ Florian Brand

Florian Brand
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Stephen Bardin, 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 24, 2023

By: /s/ Stephen Bardin
Stephen Bardin
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, 2022 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 24, 2023

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, 2022 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 24, 2023

By: /s/ Stephen Bardin
Stephen Bardin
Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

INDEX TO THE FINANCIAL STATEMENTS
Consolidated Financial Statements of COMPASS Pathways Plc

INDEX TO ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

Exhibit 99.1

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of COMPASS Pathways plc

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of COMPASS Pathways plc and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of shareholders' equity (deficit), and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2021.

Basis for Opinions

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Benefit from Research and Development Tax Credit

As described in Note 2 and 5 to the consolidated financial statements, the Company carries out research and development activities and benefits from the UK research and development ("R&D") tax credit regime under the scheme for small and medium-sized enterprises. For the year ended December 31, 2022, the Company recognized $14.4 million in benefit from R&D tax credits. As disclosed by management, they evaluate the tax credit programs the Company is expected to be eligible for and recognize a benefit from the R&D tax credit for the portion of the expense that management expects to qualify under the program and has reasonable assurance that the amount will ultimately be realized. Management assesses its research and development activities and expenditures to determine whether the nature of the activities and expenditures will qualify for credit under the tax credit program and whether the claim will ultimately be realized based on the allowable reimbursable expense criteria established by the UK government. Management makes judgements to estimate the qualifying R&D expenditures including the allocation of time spent by individual team members on R&D activities versus non-R&D activities.

The principal considerations for our determination that performing procedures relating to the benefit from research and development tax credit is a critical audit matter are (i) the significant judgement applied by management when determining the nature and amount of expenses that qualify under the tax credit program, including estimating the allocation of time spent on R&D activities; and (ii) the high degree of auditor judgement, subjectivity, and effort in performing procedures and evaluating audit evidence related to the benefit from R&D tax credit.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures also included, among others, (i) evaluating management's assessment of the nature of the activities performed by the company and their qualification for the R&D tax credit program available for small and medium sized enterprises, (ii) testing management's process for estimating R&D costs that qualify, (iii) evaluating the reasonableness of management's allocation of qualifying expenses including determining the amount expected to be realized based on relevant criteria outlined in the tax relief program, (iv) testing the completeness and accuracy of the data underlying the tax credit calculations, and (v) obtaining evidence of cash received in respect of the prior year's claim to support the assessment that the benefit will ultimately be realized.

/s/PricewaterhouseCoopers LLP

Reading, United Kingdom

February 28, 2023

We have served as the Company's auditor since 2018.

COMPASS PATHWAYS PLC
Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 143,206	$ 273,243
Restricted cash	175	104
Prepaid income tax	575	332
Prepaid expenses and other current assets	47,695	21,621
Total current assets	191,651	295,300
NON-CURRENT ASSETS:		
Investment	469	525
Property and equipment, net	617	398
Operating lease right-of-use assets	2,006	3,696
Deferred tax assets	2,224	766
Other assets	327	213
Total assets	$ 197,294	$ 300,898
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,761	$ 2,564
Accrued expenses and other liabilities	9,325	10,308
Operating lease liabilities - current	1,510	2,235
Total current liabilities	15,596	15,107
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	418	1,379
Total liabilities	16,014	16,486
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,631,794 and 42,019,874 shares authorized, issued and outstanding at December 31, 2022 and 2021, respectively	440	435
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at December 31, 2022 and 2021	28	28
Additional paid-in capital	458,825	444,750
Accumulated other comprehensive (loss)/income	(16,867)	8,840
Accumulated deficit	(261,146)	(169,641)
Total shareholders' equity	181,280	284,412

Total liabilities and shareholders' equity	$ 197,294	$ 300,898

The accompanying notes are an integral part of these consolidated financial statements.

COMPASS PATHWAYS PLC
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	Year Ended December 31,		
	2022	**2021**	**2020**
OPERATING EXPENSES:			
Research and development	$ 65,053	$ 44,027	$ 23,366
General and administrative	45,350	39,194	28,027
Total operating expenses	110,403	83,221	51,393
LOSS FROM OPERATIONS:	(110,403)	(83,221)	(51,393)
OTHER INCOME (EXPENSE), NET:			
Other income, net	4,061	40	319
Foreign exchange gains (losses)	821	1,990	(11,702)
Fair value change of convertible notes	—	—	(1,041)
Fair value change of convertible notes - due to a related party	—	—	(730)
Benefit from R&D tax credit	14,424	9,648	4,245
Total other income (expense), net	19,306	11,678	(8,909)
Loss before income taxes	(91,097)	(71,543)	(60,302)
Income tax expense	(408)	(199)	(32)
Net loss	(91,505)	(71,742)	(60,334)
Other comprehensive loss:			
Foreign exchange translation adjustment	(25,707)	(5,745)	14,683
Comprehensive loss	(117,212)	(77,487)	(45,651)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (2.16)	$ (1.79)	$ (3.55)
Weighted average ordinary shares outstanding—basic and diluted	42,436,292	39,997,587	16,991,664

The accompanying notes are an integral part of these consolidated financial statements.

COMPASS PATHWAYS PLC
Consolidated Statements of Shareholders' Equity (Deficit)
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	CONVERTIBLE PREFERRED SHARES		A CONVERTIBLE PREFERRED SHARES		B CONVERTIBLE PREFERRED SHARES		ORDINARY SHARES £0.008 PAR VALUE		DEFERRED SHARES £21,921.504 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE (LOSS)/ INCOME	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2019	**2,650,980**	**$ 3,761**	**7,131,525**	**$ 35,147**	**—**	**$ —**	**10,752,429**	**$ 111**	**—**	**$ —**	**$ 7,162**	**$ (98)**	**$ (37,565)**	**$ (30,390)**
Issuance of B convertible preferred shares, net of issuance costs	—	—	—	—	4,913,404	61,316	—	—	—	—	—	—	—	—
Conversion of notes into B convertible preferred shares	—	—	—	—	1,723,263	21,614	—	—	—	—	—	—	—	—
Exercise of share options	—	—	—	—	—	—	197,702	2	—	—	(2)	—	—	—
Exercise of share options but shares not issued	—	—	—	—	—	—	—	—	—	—	16	—	—	16
Forfeiture of ordinary shares	—	—	—	—	—	—	(63,972)	(1)	—	—	1	—	—	—
Effect of corporate reorganization including conversion of preferred shares to ordinary shares	(2,650,980)	(3,761)	(7,131,525)	(35,147)	(6,636,667)	(82,930)	16,419,172	167	1	28	121,643	—	—	121,838
Issuance of ordinary shares, net of issuance costs	—	—	—	—	—	—	8,625,000	88	—	—	132,677	—	—	132,765
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	17,983	—	—	17,983
Unrealized gain (loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	—	—	14,683	—	14,683
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(60,334)	(60,334)
Balance at December 31, 2020	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**35,930,331**	**$ 367**	**1**	**28**	**$ 279,480**	**$ 14,585**	**$ (97,899)**	**$ 196,561**
Exercise of share options	—	—	—	—	—	—	1,244,709	14	—	—	1,891	—	—	1,905
Issuance of shares due to options exercised in previous year	—	—	—	—	—	—	232,227	3	—	—	(3)	—	—	—
Issuance of ordinary shares, net of issuance costs	—	—	—	—	—	—	4,600,000	51	—	—	154,743	—	—	154,794
Issuance of ordinary shares to settle vested restricted stock units	—	—	—	—	—	—	12,607	—	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	8,639	—	—	8,639
Unrealized gain (loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	—	—	(5,745)	—	(5,745)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(71,742)	(71,742)
Balance at December 31, 2021	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**42,019,874**	**$ 435**	**1**	**28**	**$ 444,750**	**$ 8,840**	**$ (169,641)**	**$ 284,412**

Issuance of ordinary share under ATM offering, net of issuance costs	—	—	—	—	—	44,416	1	—	—	439	—	—	440
Exercise of share options	—	—	—	—	—	462,722	4	—	—	397	—	—	401
Issuance of ordinary shares to settle vested restricted stock units	—	—	—	—	—	82,622	—	—	—	—	—	—	—
Issuance of ordinary shares under 2020 employee share purchase plan	—	—	—	—	—	22,160	—	—	—	199	—	—	199
Shares tendered for withholding taxes						—	—	—	—	(83)	—	—	(83)
Share-based compensation expense						—	—	—	—	13,123	—	—	13,123
Unrealized gain (loss) on foreign currency translation						—	—	—	—	—	(25,707)	—	(25,707)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(91,505)	(91,505)
Balance at December 31, 2022	**—**	**$**	**—**	**—**	**$**	**—**	**—**	**42,631,794**	**$ 440**	**1**	**28**	**$ 458,825**	**$ (16,867)**	**$ (261,146)**	**$ 181,280**

The accompanying notes are an integral part of these consolidated financial statements.

COMPASS PATHWAYS PLC
Consolidated Statements of Cash Flows
(in thousands)
(expressed in U.S. Dollars, unless otherwise stated)

	Year Ended December 31,		
	2022	**2021**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (91,505)	$ (71,742)	$ (60,334)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	330	175	112
Change in fair value of convertible notes	—	—	1,771
Non-cash loss on foreign currency remeasurement	1,141	22	—
Non-cash share-based compensation	13,123	8,639	17,983
Non-cash lease expenses	2,126	1,797	—
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(28,760)	(8,984)	(4,490)
Deferred and prepaid tax assets	(1,701)	(877)	(221)
Other assets	(307)	(160)	(57)
Operating lease liabilities	(2,081)	(1,880)	—
Accounts payable	2,497	(163)	1,303
Accrued expenses and other liabilities	(314)	5,428	2,553
Net cash used in operating activities	(105,451)	(67,745)	(41,380)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(596)	(334)	(131)
Purchase of investments	—	—	(497)
Net cash used in investing activities	(596)	(334)	(628)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, net of issuance costs	440	154,794	—
Proceeds from the issuance of shares under the employee share purchase plan	199	—	—
Proceeds from exercise of share options	401	1,852	16
Issuance of ADRs in initial public offering, net of issuance costs	—	—	132,823
Proceeds of issuance of preferred shares, net of issuance costs	—	—	61,316
Net cash provided by financing activities	1,040	156,646	194,155
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(24,959)	(5,576)	13,225
Net (decrease)/increase in cash, cash equivalents and restricted cash	(129,966)	82,991	165,372
Cash, cash equivalents and restricted cash, beginning of the period	273,347	190,356	24,984
Cash, cash equivalents and restricted cash, end of the period	$ 143,381	$ 273,347	$ 190,356

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 783	$ 5,562	$ —
Unpaid tax withholdings on stock award recognized in accrued and other liabilities	$ 85	$ —	$ —
Proceeds from exercise of options were received and recorded in other current assets	$ —	$ 53	$ —
Deferred issuance costs included in accrued expenses	$ —	$ 856	$ —
Conversion of convertible notes into convertible preferred shares	$ —	$ —	$ 21,614

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods, shown above:

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash and cash equivalents	$ 143,206	$ 273,243	$ 190,327
Short-term restricted cash	175	104	29
Total cash, cash equivalents and restricted cash	$ 143,381	$ 273,347	$ 190,356

The accompanying notes are an integral part of these consolidated financial statements.

COMPASS PATHWAYS PLC
Notes to Consolidated Financial Statements

1. Nature of Business

COMPASS Pathways plc, or the Company, is a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health. The Company is developing its investigational COMP360 psilocybin therapy through late-stage clinical trials in Europe and North America for patients with treatment-resistant depression.

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, 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 funded its operations primarily with proceeds from the sale of its convertible preferred shares, the issuance of convertible notes, and more recently through the sale of American Depository Shares, or ADSs, in connection with the Company's initial public offering, or the IPO, in September 2020, and its $154.8 million May 2021 follow-on offering. On October 8, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, under which the Company may issue and sell from time to time up to $150.0 million of its ADSs, each representing one ordinary share, through Cowen as the sales agent. Sales of the Company's ADSs, if any, will be made at market prices. On December 14, 2022, under our at-the-market offering we sold 44,416 ADSs at $10.53 per ADS.

The Company has incurred recurring losses since its inception, including net losses of $91.5 million and $71.7 million for the years ended December 31, 2022 and 2021, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $261.1 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes the cash and cash equivalents on hand as of December 31, 2022 of $143.2 million will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months, including progressing our Phase 3 clinical program, our Phase 2 studies in anorexia nervosa and PTSD and costs associated with operating as a public company. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. We will need substantial additional funding to complete the development and commercialization of our Phase 3 clinical program, and our Phase 2 studies in anorexia nervosa and PTSD. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company may raise additional capital through a combination of equity offerings, debt financings, collaborations, and other strategic transactions, including marketing, distribution or licensing arrangements. There can be no assurance that additional funding will be available on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial conditions.

The COVID-19 pandemic and policies and regulations implemented by governments in response to the COVID-19 pandemic, most of which have been lifted, have had a significant impact, both directly and indirectly, on global businesses and commerce. For example, although restrictions in the United Kingdom and the United States have generally been lifted, additional indirect effects such as worker shortages and supply chain constraints continue to impact segments of the economy. The future extent of the impact of the COVID-19 pandemic on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations or any of the third parties on whom it relies or with whom

the Company conducts business, such as CROs or CMOs, will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the emergence of additional or more infectious variants, or the effectiveness of actions to contain and treat coronavirus.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated on consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the prepayment and accrual for research and development expenses, share-based compensation and the research and development tax credit. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. The Company does not currently have any material cash equivalents.

Restricted Cash

Restricted cash as of December 31, 2022 and 2021 represents a collateral deposit for employee credit cards.

Investment

The investment does not have readily determinable fair value and it is carried at cost, less impairment, adjusted for subsequent changes to estimated fair value up to the original cost, in circumstances where the Company does not have the ability to exercise significant influence or control over the operating and financial policies of the investee.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) 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. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the inputs for the first two are considered observable and the inputs for the last are considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

•Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques

The carrying amounts reflected in the consolidated balance sheets for the Company's cash and cash equivalents, restricted cash, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments.
The Company's convertible notes issued prior to IPO were classified within Level 3 of the fair value hierarchy because their fair values were estimated by utilizing valuation models and significant unobservable inputs. The convertible notes were valued using a scenario-based discounted cash flow analysis. Two primary scenarios were considered and probability weighted to arrive at the valuation conclusion for each convertible note. The first scenario considered the value impact of conversion at the stated discount to the issue price if the Company raised over £25.0 million in an equity financing before the first anniversary of the issuance date, the Qualified Financing, otherwise Non-Qualified Financing, while the second scenario assumed the convertible notes are held to maturity. As of the issuance date of the convertible notes, an implied yield was calculated such that the probability weighted value of the convertible note was equal to the principal investment amount. The implied yield of previously issued convertible notes was carried forward and used as the primary discount rate for subsequent valuation dates. The Company estimated the fair value of the convertible notes based on a future value on projected conversion dates which were i) discounted back to the valuation date at an appropriate discount rate and ii) probability weighted to arrive at an indication of value for the convertible notes.

Fair Value Option
As permitted under Accounting Standards Codification 825, Financial Instruments, or ASC 825, the Company has elected the fair value option to account for its convertible notes. In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the convertible notes were expensed as incurred and were not deferred. The Company concluded that it was appropriate to apply the fair value option to the convertible notes because there are no non-contingent beneficial conversion options related to the convertible notes.

Concentration of Credit Risk
Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents. The Company places cash and cash equivalents in established financial institutions. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts, or other foreign hedging arrangements.

Property and Equipment
Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

	Estimated Useful Life
Lab equipment	5 years
Office equipment	3-5 years
Furniture and fixtures	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets
The Company evaluates assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the

impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company has not recognized any impairment losses or had triggering events related to its underlying assets for the years ended December 31, 2022 and 2021.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment; however, the Company operates in two geographic regions: the United Kingdom, or UK, and the United States. The Company's fixed assets are primarily located in the UK. The Company's singular concentration is focused on accelerating patient access to evidence-based innovation in mental health.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, travel, and external costs of outside vendors engaged to conduct clinical development activities, clinical trials and the cost to manufacture clinical trial materials.

Research Contract Costs, Prepayments and Accruals

The Company has entered into various research and development-related contracts with research institutions and other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records prepayments and accruals for estimated ongoing research costs and receives updated estimates of costs and amounts owed on a monthly basis from its third-party service providers. When evaluating the adequacy of the prepayments and accruals, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted cost estimates from third-party service providers. Estimates are made in determining the prepaid and accrued expense balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical prepayments and accrual estimates have not been materially different from the actual costs.

Share-Based Compensation

The Company accounts for all share-based payment awards granted to employees and non-employees as share-based compensation expense at fair value. The Company grants equity awards under its share-based compensation programs, which may include share options and restricted stock units. The measurement date for employee and non-employee awards is the date of grant, and share-based compensation costs are recognized as an expense over the requisite service period, which is the vesting period, on a straight-line basis. Share-based compensation expense is classified in the accompanying consolidated statements of operations and comprehensive loss based on the function to which the related services are provided. The Company recognizes share-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

On October 1, 2021, the Company launched the Share Incentive Plan, or the SIP, and Employee Share Purchase Plan, or the ESPP, through which employees can purchase shares at a discounted price. The Company estimated the fair value of stock options and shares to be issued under the SIP and ESPP using the Black-Scholes option-pricing model on the date of grant. The fair value of shares to be issued under these plans are recognized and amortized on a straight-line basis over the purchase period, which is generally six months.

There have been no performance conditions attached to the share options granted by the Company to date. The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 11 for the Company's assumptions used in connection with option grants made during the periods covered by these consolidated financial statements. Assumptions used in the option pricing model include the following:

Expected volatility. The Company lacks sufficient company-specific historical and implied volatility information for its ordinary shares. Therefore, it estimates its expected share volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Expected term. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The "simplified" method was determined to be appropriate as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded.

Risk-free interest rate. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

Fair value of ordinary shares. Given the absence of an active market for the Company's ordinary shares prior to the IPO, the Company and the board of directors of the Company, the members of which the Company believes have extensive business, finance, and venture capital experience, were required to estimate the fair value of the Company's ordinary shares at the time of each grant of a stock-based award prior to the IPO. The grant date fair value of restricted ordinary shares and share options were calculated based on the grant date fair value of the underlying ordinary shares. The Company calculated the fair value of the ordinary shares in accordance with the guidelines in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the "Practice Aid". The Company's valuations of ordinary shares were prepared using a market approach, based on precedent transactions in the shares, to estimate the Company's total equity value using an option-pricing method, or OPM. After the Company's IPO, the fair value of ordinary shares is determined by reference to the closing price of ADSs on the Nasdaq Global Select Market on the day prior to or day of the grant.

The OPM derives an equity value such that the value indicated for ordinary shares is consistent with the investment price, and it provides an allocation of this equity value to each of the Company's securities. The OPM treats the various classes of ordinary shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the ordinary shares have value only if the funds available for distribution to shareholders exceeded the value of the share liquidation preferences of ordinary shares with senior preferences at the time of the liquidity event. Key inputs into the OPM calculation included the risk-free rate, expected time to liquidity and volatility. A reasonable discount for lack of marketability was applied to the total equity value to arrive at an estimate of the total fair value of equity on a non-marketable basis.

Leases

Effective January 1, 2021, the Company adopted ASU No. 2016-02, Leases (Topic 842), as amended, using the modified retrospective method and utilizing the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840, Leases, or ASC 840. The Company has elected to apply the package of three expedients to all of its leases requiring (1) no reassessment of whether any expired or existing contracts are or contain leases, (2) the lease classification of any expired or existing leases, or (3) the capitalization of initial direct costs for any existing leases. Adoption of this standard resulted in the recording of operating lease right-of-use assets and current operating lease liabilities of $1.0 million, on the Company's balance sheet on the effective date. The adoption of the standard did not have a material effect on the Company's statements of operations and comprehensive loss, statements of cash flows or

accumulated deficit. Refer to Note 14 for right-of-use assets and liabilities recorded during the periods ended December 31, 2022 and 2021 respectively.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and to allocate all the contract consideration to the lease component only. All the Company's leases are classified as operating leases.

Lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts has not been readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. As the Company does not have a rating agency-based credit rating, quotes were obtained from lenders to establish an estimated secured rate to borrow based on Company and market-based factors as of the respective lease measurement dates. The Company has elected not to recognize leases with an original term of one year or less on the balance sheets. The Company typically only includes the non-cancelable lease term in its assessment of a lease arrangement unless there is an option to extend the lease that is reasonably certain of exercise. The Company adjusts the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Operating lease costs are recognized on a straight-line basis over the lease term, and they are categorized within research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss. The operating lease cash flows are categorized under net cash used in operating activities in the consolidated statements of cash flows.

Foreign Currency Translation

The Company maintains its consolidated financial statements in its functional currency, which is Pound Sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company recorded foreign exchange gains of approximately $0.8 million and $2.0 million for the years ended December 31, 2022 and 2021, respectively. These gains arise from U.S. dollars which are held in a financial institution in one of our UK subsidiaries that has a functional currency of Pound Sterling.

For financial reporting purposes, the consolidated financial statements of the Company have been presented in the U.S. dollar, the reporting currency. The financial statements of entities are translated from their functional currency into the reporting currency as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, expenses and other income (expense), net are translated at the average exchange rates for the periods presented and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to other comprehensive income, a component of shareholders' equity.

Income Taxes

In December 2019, the FASB issued Accounting Standard Update, or ASU, 2019-12, "Income Taxes - Simplifying the Accounting for Income Taxes (Topic 740)," or ASU 740, which simplifies the accounting for income taxes. The new guidance removes certain exceptions to the general principles in ASC 740 such as recognizing deferred taxes for equity investments, the

incremental approach to performing intra-period tax allocation and calculating income taxes in interim periods. The standard also simplifies accounting for income taxes under U.S. GAAP by clarifying and amending existing guidance, including the recognition of deferred taxes for goodwill, the allocation of taxes to members of a consolidated group and requiring that an entity reflect the effect of enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. This guidance is effective for annual periods beginning after December 15, 2020, and interim periods thereafter; however, early adoption is permitted. The Company adopted this ASU as of January 1, 2021 and it has had no material impact on the consolidated financial statements.

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in its tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered in the future to the extent management believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefit that may be used is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. As of December 31, 2022 and 2021, the Company has not identified any material uncertain tax positions.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2021 no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheets.

Benefit from Research and Development Tax Credit

As a company that carries out extensive research and development activities, the Company benefits from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises, or SME. Under the SME regime, the Company is able to surrender some of its trading losses that arise from qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditure. The Company meets the conditions of the SME regime. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects. Certain subcontracted qualifying research and development expenditures are eligible for a cash rebate of up to 21.67%. A large portion of costs relating to research and development, clinical trials and manufacturing activities are eligible for inclusion within these tax credit cash rebate claims.

The Company is subject to corporate taxation in the UK. Due to the nature of the business, the Company has generated losses since inception. The benefit from research and development, or R&D, tax credits is recognized in the consolidated statements of operations and comprehensive loss as a component of other income (expense), net, and represents the sum of the research and development tax credits recoverable in the UK.

The UK research and development tax credit is fully refundable to the Company and is not dependent on current or future taxable income. As a result, the Company has recorded the entire benefit from the UK research and development tax credit as a benefit which is included in net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any UK research and development tax credits generated are needed to offset a corporate income tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded within other income (expense), net.

The Company may not be able to continue to claim research and development tax credits under the SME regime in the future because it may no longer qualify as a small or medium-sized company. In addition, the EU State Aid cap limits the total aid claimable in respect of a given project to €7.5 million which may impact the Company's ability to claim R&D tax credits in future. Further, the U.K. Finance Act of 2021 introduced a cap on credit claims under the SME Program in excess of £20,000 with effect from April 2021 by reference to, broadly, three times the total Pay As You Earn, or PAYE, and National Insurance Contributions, or NICs, liability of the company, subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties, which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim. In the Finance Act 2022-23, the rates for the SME R&D regime were reduced such that for expenditure from April 1, 2023 the effective credit will reduce from 33.4p/£ to 18.6p/£.

Unsurrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of UK taxable profits.

Comprehensive Loss
Comprehensive loss includes net loss as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders. For the years ended December 31, 2022 and 2021, the only component of accumulated other comprehensive loss is foreign currency translation adjustment.

Net Loss per Share
The Company has reported losses since inception and has computed basic net loss per share attributable to ordinary shareholders by dividing net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per ordinary share after giving consideration to all potentially dilutive ordinary shares, including unvested restricted shares and outstanding options. Because the Company has reported net losses since inception, these potential ordinary shares have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

Derivatives
The Company enters into foreign currency contracts to reduce the risk that our cash flows and earnings will be adversely affected by foreign currency exchange rate fluctuations. The Company does not enter into foreign currency contracts for speculative purposes. The Company recognizes derivative instruments, which do not qualify for hedge accounting, as either assets or liabilities on the balance sheet at fair value. The Company records changes in the fair value (gains or losses) of the derivatives in the accompanying consolidated statement of operations and comprehensive loss as other income (expense), net.

Recently Issued Accounting Pronouncements
The Company reviewed recently issued accounting pronouncements and determined there will not be an impact to our financial position and results of operations.

3. Fair Value Measurements

There are no financial instruments measured at fair value on a recurring basis as of December 31, 2022 and 2021. Management believes that the carrying amounts of the Company's consolidated financial instruments, including cash and cash equivalents, restricted cash, accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

The Company elected the fair value option to account for its convertible notes issued during 2019 (See Note 8). The fair value of the convertible notes was determined based on significant inputs not observable in the market, which represents a level 3 measurement within the fair value hierarchy.

The Company recorded a loss of $1.8 million for changes in the fair value of the convertible notes in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020.

The following table provides a roll forward of the aggregate fair value of the Company's convertible notes, for which fair value was determined using level 3 inputs (in thousands):

	Convertible Notes
Balance as of December 31, 2019	$ 21,089
Change in fair value	1,771
Settlement of convertible notes	(21,614)
Exchange difference	(1,246)
Balance as of December 31, 2020, 2021 and 2022	$ —

4. Investment

On March 6, 2020, the Company made a strategic investment of $0.5 million to acquire an 8% (on a fully diluted basis) shareholding in Delix Therapeutics, Inc., a drug discovery and development company researching novel small molecules for use in Central Nervous System, or CNS, indications. The Company's investment in Delix Therapeutics, Inc. does not provide it with significant influence over the investee. The investment does not have a readily determinable fair value and therefore will be measured at cost minus impairment adjusted by observable price changes in orderly transactions for the identical or a similar investment of the same issuer. This investment will be measured at fair value on a nonrecurring basis when there are events or changes in circumstances that may have a significant adverse effect. An impairment loss is recognized in the consolidated statements of operations and comprehensive loss equal to the amount by which the carrying value exceeds the fair value of the investment. As of December 31, 2022, no impairment loss was recognized.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
UK R&D tax credit	$ 13,972	$ 9,587
Prepaid insurance premium	2,818	3,359
Prepaid research and development	28,211	4,562
VAT recoverable	1,652	1,629
Deferred offering costs	—	840
Security deposit	97	274
Other current assets	945	1,370
	$ 47,695	$ 21,621

6. Property and Equipment, Net

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

	December 31,	
	2022	2021
Lab equipment	$ 332	$ 370
Office equipment	637	315
Furniture and fixtures	87	65
Leasehold improvements	91	6
	1,147	756
Less: accumulated depreciation	(530)	(358)
	$ 617	$ 398

Depreciation and amortization expenses were $0.3 million, $0.2 million and $0.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

7. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued research and development expense	$ 1,684	$ 3,043
Accrued professional expenses	1,284	1,386
Accrued compensation and benefit costs	5,534	5,018
Payroll tax payable	167	593
Other liabilities	656	268
	$ 9,325	$ 10,308

8. Convertible Notes

On April 17, 2020, upon the Series B convertible preferred share financing, which constituted a Qualified Financing, the outstanding principal of the convertible notes of $18.4 million (£15.0 million) automatically converted into 1,723,263 Series B convertible preferred shares, and there was no outstanding balance as of December 31, 2020.

The Company elected the fair value option to account for the 2019 Convertible Notes. The Company recorded the 2019 Convertible Notes at fair value and subsequently remeasured them to fair value at each reporting date. Changes in fair value were recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company recognized losses in the consolidated statements of operations and comprehensive loss of $1.8 million as change in fair value of the convertible notes during the year ended December 31, 2020. There are no convertible notes outstanding in the years ended December 31, 2022 or 2021.

9. Convertible Preferred Shares

On April 17, 2020, the Company closed a Series B funding round to secure an additional $80.0 million of funding, including the conversion of the 2019 Convertible Notes (see Note 8), through the issuance of Series B convertible preferred shares. The Company received $61.6 million in cash proceeds upon the issuance of 4,913,404 Series B convertible preferred shares and incurred issuance costs of $0.3 million, recorded as a reduction to the convertible preferred shares. The 2019 Convertible Notes were converted into 1,723,263 Series B convertible preferred shares. The issuance price of the Series B convertible preferred shares was $1.42 per share.

Convertible preferred shares and Series A convertible preferred shares consisted of the following as of December 31, 2019 (in thousands, except for share amounts):

	Shares		Liquidation Preference	Carrying Value
	Authorized	Outstanding		
Convertible preferred shares	2,650,980	2,650,980	$ 3,865	$ 3,761
Series A convertible preferred shares	7,131,525	7,131,525	35,414	35,147
	9,782,505	9,782,505	$ 39,279	$ 38,908

Upon closing of the IPO, the convertible preferred shares and Series A convertible preferred shares as of December 31, 2019, together with the Series B convertible preferred shares issued during the year ended December 31, 2020, were converted to 16,419,172 ordinary shares. The holders of the Company's convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares had certain voting, dividend, and redemption rights, as well as liquidation preferences and conversion privileges. All rights, preferences, and privileges associated with the convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares were terminated at the time of the Company's IPO in conjunction with the conversion of all outstanding convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares into ordinary shares.

10. Ordinary Shares

On September 22, 2020, the Company closed its IPO of ADSs representing its ordinary shares and issued and sold 8,625,000 ADSs at a public offering price of $17.00 per ADS, resulting in net proceeds of approximately $132.8 million after deducting underwriting fees and offering costs. Upon the closing of the IPO, the convertible preferred shares and Series A convertible preferred shares and Series B convertible preferred shares were converted to 16,419,172 ordinary shares.

On May 4, 2021, the Company sold 4,000,000 ordinary shares in connection with its follow-on offering. On May 19, 2021 the underwriters exercised their option to purchase an additional 600,000 ordinary shares. This capital raise resulted in net proceeds of approximately $154.8 million after deducting underwriting fees and offering costs.

Each ordinary share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends, if any, as may be declared by the board of directors. Through December 31, 2022, no cash dividends had been declared or paid by the Company.

On October 8, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, under which the Company may issue and sell from time to time up to $150.0 million of its ADSs, each representing one ordinary share, through Cowen as the sales agent. Sales of the Company's ADSs, if any, will be made at market prices. On December 14, 2022, under our at-the-market offering we sold 44,416 ADSs at $10.53 per ADS.

During the year ended December 31, 2021, the Company issued in total 1,476,936 ordinary shares to settle share options exercised by employees and non-employees, of which 232,227 ordinary shares related to options exercised in 2020, with subsequent share issuances in 2021. During the year ended December 31, 2022, the Company issued in total 462,722 ordinary shares to settle share options exercised by employees and non-employees.

During the year ended December 31, 2021, a total of 70,482 restricted share units vested, of which 12,607 shares were vested and issued in settlement and 57,875 shares were vested but had not been issued at December 31, 2021.

During the year ended December 31, 2022, a total of 42,635 restricted share units vested, of which 24,747 shares were vested and issued in settlement and 17,888 shares were vested but had not been issued at December 31, 2022. During 2022, a total of 82,622 shares were issued in settlement, of which 57,875 vested in 2021 and 24,747 vested in 2022.

During the years ended December 31, 2022 and 2021, the Company issued in total 22,160 and 0 shares under the employee share purchase plans.

11. Share-Based Compensation

2017 Equity Incentive Plan

Under the Company's historical shareholder and subscription agreements, the Company was authorized to issue restricted shares, restricted share units, as well as options, as incentives to its employees, non-employees and members of its board of directors. To the extent such incentives were in the form of share options, the options were granted pursuant to the terms of the 2017 Equity Incentive Plan, or the 2017 Plan. In July 2019, the Company's board of directors adopted the 2017 Plan. The 2017 Plan provided for the grant of Enterprise Management Incentive, or EMI, options, to its UK employees, for the grant of options to its U.S. employees and non-employees of the Company. The 2017 Plan was administered by the board of directors.

Options granted under the 2017 Plan, typically vest over a three or four-year service period with 33.3% and 25% respectively, of the award vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years. Options granted under the 2017 Plan generally expire 10 years from the date of grant. Restricted share units granted under the 2017 Plan typically vest over a four-year service period with 25% of the award vesting on the first anniversary of the commencement date and quarterly thereafter.

The options granted on June 30, 2020 were subject to 25% vesting upon the earlier occurrence of (i) the one year anniversary of the date of grant, or (ii) the date of the listing of the Company's ordinary shares on any stock exchange, followed by straight line vesting for three years for the remaining 75% of the allocation until vested in full.

The restricted share units granted on June 30, 2020 were subject to 25% vesting upon the earlier of (i) the one year anniversary of the date of grant, or (ii) the first day following the six-month anniversary of the listing of the Company's ordinary shares on any stock exchange on which the closing price of the shares is 20% higher than the listing price for at least five consecutive trading days.

As of December 31, 2022, the Company was authorized to issue a total of 1,603,402 ordinary shares underlying outstanding options granted under the 2017 Plan prior to the IPO.

2020 Employee Share Purchase Plan

The Company's 2020 Employee Share Purchase Plan, or the ESPP, was adopted by the Board in September 2020 and approved by shareholders in September 2020 and became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The ESPP initially reserved and authorized the issuance of up to a total of 340,053 ordinary shares to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through termination of the 2020 Plan, by the lesser of (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31, (ii) 510,080 ordinary shares or (iii) such lesser number of ordinary shares as determined by the plan administrator. The number of shares reserved under the ESPP is subject to change in the event of a share split, share dividend or other change in our capitalization.

On October 1, 2021, the Company launched the SIP and the ESPP, through which employees can purchase shares at a discounted price. At the end of six months, shares will automatically be purchased at the lower of the opening and closing price of the shares for the saving period minus a 15% discount.

2020 Share Option Plan

In September 2020, the Company's board of directors adopted, and the Company's shareholders approved, the 2020 Share Option and Incentive Plan, or the 2020 Plan, which became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The 2020 Plan allows the compensation and leadership development committee to make equity-based and cash-based incentive awards to the Company's officers, employees, directors and other key persons (including consultants).

Options granted under the 2020 Plan generally expire 10 years from the date of grant and typically vest over a 4 year service period with 25% of the options vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years.

The Company initially reserved 2,074,325 of its ordinary shares for the issuance of awards under the 2020 Plan. The 2020 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by up to 4% of the outstanding number of ordinary shares on the immediately preceding December 31, or such lesser number of shares as determined by our compensation and leadership development committee. This number is subject to adjustment in the event of a sub-division, consolidation, share dividend or other change in our capitalization. The total number of ordinary shares that may be issued under the 2020 Plan is 3,755,119 shares as of December 31, 2022, of which 667,802 shares remained available for future grant.

The options granted in 2022 under the 2020 Plan to employees generally expire 10 years from the date of grant. There are three potential vesting terms for the 2022 grants including: (i) 25% per year over four year service period, (ii) four year service period with 25% of the vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining years; and (iii) monthly vesting over four year service period.

During the years ended December 31, 2022, 2021 and 2020, the Company granted options to purchase 2,120,783, 1,043,702 and 3,405,490 ordinary shares to employees and non-employees, respectively.

2022 Inducement Option Award

On August 1, 2022, the Company granted to our new chief executive officer a non-qualified share option to purchase up to 600,000 ordinary shares as an inducement grant. The non-qualified share option has a 10 year term and vests as to one-fourth on August 1, 2023 and as to the remaining three-fourths in equal monthly installments over the following 36 months. The non-qualified share option has other terms that mirror those of non-qualified share options granted under the Company's 2020 Plan and the Company's standard form of non-qualified share option agreement.

Ordinary Shares

A summary of the changes in the Company's unvested ordinary shares during the year ended December 31, 2022, 2021 and 2020 are as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2020	13,757	$ 2.36
Granted	—	$ —
Vested	(13,757)	$ 2.36
Forfeited	—	$ —
Unvested and Outstanding as of December 31, 2022 and 2021	—	$ —

The total fair value of vested shares was nil, less than $0.1 million and $1.3 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Restricted Share Units

A summary of the changes in the Company's unvested restricted share units during the years ended December 31, 2022, 2021 and 2020 are as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2020	217,482	$ 10.19
Granted	—	—
Vested	(70,482)	10.19
Forfeited	(31,860)	10.19
Unvested and Outstanding as of December 31, 2021	115,140	$ 10.19
Granted	202,830	13.52
Vested	(42,635)	9.77
Forfeited	(4,200)	14.44
Unvested and Outstanding as of December 31, 2022	271,135	$ 12.23

As of December 31, 2022, 2021 and 2020, there was $2.6 million, $1.2 million and $2.0 million of unrecognized compensation cost related to unvested restricted share units, respectively, which is expected to be recognized over a weighted-average period of 2.95 years, 2.5 years and 3.2 years, respectively. The exercise price of restricted share units is at a nominal value less than £0.01 per share.

Share Options

The following table summarizes the Company's share options activity for the years ended December 31, 2022, 2021 and 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	4,430,340	$ 5.61	9.22	$ 186,426
Granted	1,043,702	$ 36.11		
Exercised	(1,244,709)	$ 1.55		
Cancelled or forfeited	(313,830)	$ 22.45		
Outstanding as of December 31, 2021	3,915,503	$ 13.53	8.64	$ 51,162
Granted	2,120,783	$ 13.49		
Exercised	(462,722)	$ 0.75		
Cancelled or forfeited	(480,832)	$ 11.09		
Outstanding as of December 31, 2022	5,092,732	$ 13.55	8.38	$ 13,013
Exercisable as of December 31, 2022	2,342,389	$ 9.14	7.67	$ 11,765
Unvested as of December 31, 2022	2,750,343	$ 17.31	8.99	$ 1,247

The aggregate intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020 was $5.5 million, $47.4 million and $12.8 million, respectively.

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares.

The weighted average grant-date fair value of share options granted was $10 and $21.35 and $9.83 per share during the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, 2021 and 2020, there was $30.4 million, $27.4 million and $18.1 million of unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of 2.8 years, 3.1 years and 3.5 years respectively.

Share Option Valuation

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the years ended December 31, 2022, 2021 and 2020 were as follows:

	Year Ended December 31,		
	2022	**2021**	**2020**
Expected option life (years)	5.95 years	5.73 years	5.95 years
Expected volatility	80.76 %	67.36 %	66.10 %
Risk-free interest rate	2.26 %	0.95 %	0.43 %
Expected dividend yield	— %	— %	— %
Fair value of underlying ordinary shares	$ 14.06	$ 35.21	$ 12.58

Share-based Compensation Expense

Share-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Research and development	7,358	4,569	6,336
General and administrative	5,765	4,070	11,647
Total stock based compensation expense	$ 13,123	$ 8,639	$ 17,983

12. Income Taxes

Income (loss) before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
United Kingdom	(92,841)	(72,397)	(60,522)
Foreign	1,744	854	220
Loss before provision for income taxes	(91,097)	(71,543)	(60,302)

The provision for income taxes for the years ended December 31, 2022, 2021 and 2020 was computed at the UK statutory income tax rate. The income tax provision for the years then ended comprised (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Current income tax provision			
United Kingdom	$ —	$ —	$ —
Foreign	1,865	744	253
Total current expense:	$ 1,865	$ 744	$ 253
Deferred income tax benefit:			
United Kingdom	—	—	—
Foreign	(1,457)	(545)	(221)
Total deferred income tax benefit:	$ (1,457)	$ (545)	$ (221)
Total provision for income taxes	$ 408	$ 199	$ 32

A reconciliation of income tax expense computed at the statutory UK income tax rate to income taxes as reflected in the consolidated financial statements is as follows (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Income taxes at UK statutory rate	$ (17,309)	$ (13,592)	$ (11,458)
Permanent differences	14	69	340
UK R&D tax credit	5,423	3,747	1,664
Change in valuation allowance	15,038	29,180	8,683
State income taxes	10	1	(5)
Deferred tax asset true-up	8	80	919
Return to Provision	1,580	(854)	—

Equity Compensation	(782)	(8,302)	—
Change in UK Tax Rate	(3,609)	(10,147)	—
Other	35	17	(111)
	$ 408	$ 199	$ 32

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022, 2021 and 2020 consist of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net operating loss carryforward	$ 44,227	$ 35,947	$ 10,075
Reserves and accruals	695	169	62
Share-based compensation	9,332	6,232	3,128
Charitable contributions	33	—	—
Total deferred tax assets	54,287	42,348	13,265
Valuation allowance	$ (51,909)	$ (41,483)	$ (13,000)
Depreciation	(154)	(99)	(44)
Total deferred tax liabilities	(154)	(99)	(44)
Net deferred tax assets	$ 2,224	$ 766	$ 221

As of December 31, 2022, 2021 and 2020, the Company had UK net operating loss carryforwards of approximately $176.9 million, $144.0 million and $53.0 million, respectively, that can be carried forward indefinitely.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2022, 2021 and 2020 related primarily to the increases in net operating loss and were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Valuation allowance at beginning of year	$ 41,483	$ 13,000	$ 3,665
Increases recorded to income tax provision	15,038	29,180	8,683
Increases recorded to CTA	—	—	652
Decreases recorded to CTA	(4,612)	(697)	—
Valuation allowance at end of year	$ 51,909	$ 41,483	$ 13,000

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2022, 2021 and 2020, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance against its net UK deferred tax assets as of December 31, 2022, 2021 and 2020. The deferred tax asset recognized relates entirely to the US entity.

The Company applies the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. There were no material uncertain tax positions as of December 31, 2022, 2021 and 2020.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense when in a taxable income position. As of December 31, 2022, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

The Company and its subsidiaries file income tax returns in the UK and U.S. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the federal, state, or foreign tax authorities, if such tax attributes are utilized in a future period.

During the second quarter of 2021, the Finance Act 2021 (the Act) was enacted in the United Kingdom. The Act increases the corporate income tax rate from 19% to 25% effective April 1, 2023 and enhances the first-year capital allowance on qualifying new plant and machinery assets effective April 1, 2021. The effects on the Company's existing deferred tax balances have been recorded and is offset by the valuation allowance maintained against the Company's U.K. net deferred tax assets.

13. Net Loss Per Share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2022	**2021**	**2020**
Numerator			
Net loss	$ (91,505)	$ (71,742)	$ (60,334)
Net loss attributable to ordinary shareholders - basic and diluted	$ (91,505)	$ (71,742)	$ (60,334)
Denominator			
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	42,436,292	39,997,587	16,991,664
Net loss per share - basic and diluted	$ (2.16)	$ (1.79)	$ (3.55)

The Company's potentially dilutive securities, which include unvested ordinary shares, unvested restricted share units, and options granted, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of ordinary shares outstanding used to calculate both basic and diluted net loss per share attributable to ordinary shareholders is the same. The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to ordinary shareholders for the years ended December 31, 2022, 2021 and 2020 because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2022	**2021**	**2020**
Unvested restricted share units	271,135	115,140	217,482
Unvested ordinary shares	—	—	13,757
Vested restricted share units, for which shares are not in issue	17,888	57,875	—
Share options	5,092,732	3,915,503	4,430,340
	5,381,755	4,088,518	4,661,579

14. Right of use of assets:

New York, USA

In August 2022, the Company entered into a twelve month membership agreement with WeWork for rentable office space. The membership is cancellable with 90 days' notice. This membership is accounted for as a short-term lease as the Company is not reasonably certain to extend the lease beyond twelve months and is therefore not recognized on the Company's consolidated balance sheets.

Soho, London, UK

In July 2021, the Company entered into a two-year operating lease with Fora Space Limited commencing on September 1, 2021. The noncancellable term is 24 months and there is no option to extend the lease. The recurring residency fee per month is £136,200, and the Company paid a refundable deposit of £136,200 at the execution of the agreement. Additionally, at the start of each calendar year, the monthly residency fee will be subject to an automatic inflation linked increase of the previous years' amount.

Denmark Hill, London, UK

In March 2022, the Company entered into an agreement for a lease with South London and Maudsley NHS Foundation Trust for land and buildings at 5 Windsor Walk, Maudsley Hospital, Denmark Hill, London, UK. The lease commenced on June 21, 2022 and has a contractual term of five years. The rent is £180,000 per year, with no deposit payable.
The following table summarizes our costs included in our consolidated statements of operations and comprehensive loss related to right of use lease assets we have entered for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	**2021**
Lease cost		
Operating lease cost	$ 2,263	$ 1,844
Variable lease cost	—	—
Short-term lease cost	256	86
	$ 2,519	$ 1,930
Other information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	$ 2,219	$ 1,971
Right-of-use assets obtained in exchange for new operating lease liabilities	783	4,513
Weighted average remaining lease term (in years)	1.58	1.64
Weighted average discount rate	5.70 %	4.99 %

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2022, (in thousands):

December 31, 2023		1,537
December 31, 2024		218
December 31, 2025		218
December 31, 2026		54
Total future minimum lease payments	$	2,027
Less: imputed interest		(99)
Total	$	1,928

15. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. The Company was not a party to any material litigation and did not have material contingency reserves established for any liabilities as of December 31, 2022, 2021 or 2020.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its Articles of Association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

16. Employee Benefit Plans

In the UK, the Company makes contributions to private defined contribution pension schemes on behalf of its employees. The Company paid $0.2 million, $0.2 million and less than $0.1 million in contributions for the years ended December 31, 2022, 2021, and 2020 respectively.

In the United States, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company paid $0.2 million, $0.1 million and less than $0.1 million in contributions in the years ended December 31, 2022, 2021 and 2020, respectively.