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, 2021

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. c/o Mindspace **Krausenstraße 9-10** **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. ☐

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, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $2.05 billion. 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, 2022, the registrant had 160,709,397 common shares, par value €0.10 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2022 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, 2021, 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, 2021 (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, including 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 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, potential acquisitions, and the plans and objectives of management for future operations and capital expenditures, are forward-looking statements. 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 "Risk Factor Summary" 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, 2021.

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; to become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue;

- 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;
- Our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability;
- 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 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 rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances;
- 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 cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized, or that our product candidates will ultimately succeed;
- 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;
- We face significant competition in an environment of rapid technological and scientific change and our competitors may discover, develop or commercialize therapies before or more successfully than us, which may result in the reduction or elimination of our commercial opportunities;
- 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 ability to retain key employees, directors, consultants and advisors, including key management of us or our product candidate portfolio companies and respective scientific personnel may limit our growth strategy;
- A change in our effective place of management may increase our aggregate tax burden;
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate the material weaknesses, or if other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner;
- Our business is subject to economic, political, regulatory and other risks associated with international operations; and
- 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.

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 as a 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, including psychedelic compounds and digital therapeutics and, on June 22, 2021, we closed the initial public offering ("IPO") of our common shares on the Nasdaq Stock Market ("Nasdaq").

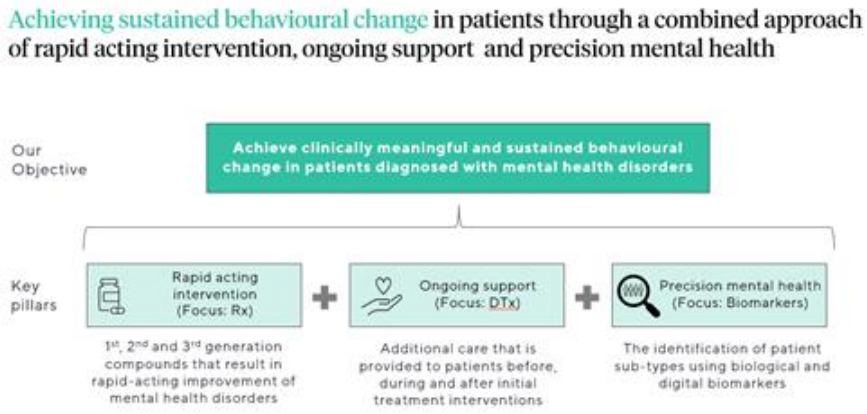
Our Business and Strategy
We have a bold and ambitious vision: to heal mental health disorders so that everyone, everywhere can live a more fulfilled life.

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. Additionally, it is expected that more than 50% of the U.S. population will be diagnosed with a mental health disorder at some point in their lifetime. Most recently, the COVID-19 pandemic has had a negative impact on mental health and has resulted in an increasing incidence, with depression rates reported to have increased threefold compared to those reported pre-pandemic. Those suffering from mental health disorders have higher mortality rates than the general population and often experience decreased quality of life as a result of emotional, behavioral or physical manifestations. 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.

We have built a pipeline of 13 drug and discovery development programs and four enabling technologies, each led by focused teams with deep expertise in their respective fields and supported by our internal development and operational infrastructure. We believe that several of our therapeutic programs' target indications have potential market opportunities of at least $1 billion in annual sales, if approved.

Our business is organized along three strategic pillars:

- **Rapid acting intervention**: first, second, and third generation compounds that result in rapid-acting improvement of mental health disorders;
- **Ongoing digital support**: additional care that is provided to patients before, during, and after initial treatment interventions; and
- **Biomarker-driven precision mental health**: the identification of patient sub-types using biological and digital biomarkers.



We operate a decentralized model to enable scalable drug or technological development at our atai companies. Our atai companies drive development of our programs and enabling technologies 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 therapeutic candidates or technologies 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.

Our Platform

To support the ongoing growth of our pipeline and the development of our existing programs, we have established a platform that underpins our operations. Our platform consists of our process, our people and our enabling technologies.

Our Process

Our process comprises three core elements: (i) disciplined new program selection, focusing on differentiated mental health opportunities encompassing psychedelic compounds and nonpsychedelic compounds, (ii) decentralized operations with access to shared resources, which we believe facilitates scalable drug or technological development in a capital efficient manner, and (iii) impactful capital allocation and strategic value capture.

Disciplined New Program Selection

We focus on differentiated mental health opportunities that we believe present significant commercial potential and a high probability of clinical success based on screening along certain criteria, including the following:

- **Therapeutic focus in mental health.** We are focused on developing innovative therapeutics for mental health disorders based on new insights into the brain's response to therapies that may previously have been overlooked or underused, including psychedelic compounds, nonpsychedelic compounds and digital therapeutics. Despite a previous stigma, psychedelics are emerging as novel breakthrough therapies for mental health disorders, such as depression and SUD, 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.

- **Prior evidence in humans**. We prioritize the development of compounds and compound classes that have shown potential for efficacy and safety in prior clinical trials or observational studies.

- **Differentiated pharmacological and treatment effect**. We prioritize the development of compounds with novel pharmacological characteristics including the potential for rapid onset, enhanced efficacy and improved tolerability. Our programs include natural products and their derivatives that have not previously been formally developed as drugs, as well as de novo compounds.

- **Rapid clinical proof of concept**. Our approach to research and development involves defining discrete de-risking steps that constitute go/no-go decision points. Our clinical development strategy is focused on obtaining clinical proof of concept from modestly sized, short duration trials where a clinical effect or a biomarker of efficacy can be observed before investing in larger trials.

- **Significant commercial opportunity.** We prioritize opportunities that we believe, if approved, have a peak sales potential of $1 billion or more.

- **Potential synergies with our existing pipeline.** We intend to pursue opportunities which align with our selection criteria and for which we believe we have a competitive advantage due to synergies with our existing knowledge, capabilities, infrastructure, pipeline programs and enabling technologies, among others.

Decentralized Operations with Access to Shared Resources

We operate a decentralized model to enable scalable drug or technological development. Our atai companies are led by teams dedicated to advancing their respective therapeutic candidates. 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. Key elements of our operating model include:

- **Shared operational backbone.** Our central organization provides operating leverage to our teams by providing shared services and expertise, such as scientific insight, intellectual property, strategy, data analytics and clinical and regulatory support.

- **Efficient cost structure.** We believe our shared operational model enables us to minimize overhead costs that may otherwise be incurred by individual companies that are required to build out full non-research and development support functions and fixed cost infrastructure, despite relatively small pipelines.

- **Entrepreneurial incentives and decentralized decision making**. Each program is supported by a team of experts and specialists who are incentivized to achieve success. For subsidiaries that we have acquired, the management teams hold equity interests in those particular entities, thus providing equity incentives at the program level. This creates an intense focus on advancing drug candidates for patients. Though ultimate oversight of our company is at the atai level, our structure includes certain operational determinations made by respective management and stakeholders closest to the programs, which we believe results in faster and more effective program management.

- **Network of academic and business leaders**. Our broad focus on developing therapeutics for the treatment of mental health disorders benefits from our network of advisors that includes many of the leading experts in the mental health field. In addition, a number of scientific advisory board members at both atai and our subsidiaries guide the development of each of our programs.

Impactful Capital Allocation and Strategic Value Capture
We look to optimize deployment of our capital in order to maximize value for our stakeholders. Key components of our approach include:

- **Diversified pipeline.** We have built a pipeline of 13 drug and discovery development programs that vary across stage of development, indication and mechanism of action and we intend to add further programs to our pipeline, which we believe will improve the commercial potential and risk profile of our pipeline in the aggregate. We believe our programs are clinically uncorrelated, which has the potential to mitigate the impact of any single program failure. In addition, we also have four enabling technologies to help support the development of our pipeline and be used as patient support tools.

- **Discrete de-risking decision points**. Our approach to research and development involves defining discrete de-risking steps that constitute go/no-go decision points in the development of our programs. This approach allows each atai company to focus on achieving their next milestone and provides us with appropriate control over each program. If our programs do not meet our criteria for advancement at a particular stage, we will discontinue the program in order to focus our resources and capital more effectively.

- **Optimized value capture.** We intend to provide the necessary funding and operational support to our programs to maximize their probability of success in clinical development and commercialization. However, we 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.

Our People
We were founded by Christian Angermayer, a prominent biotech investor and the founder of Apeiron Investment Group Ltd. (“Apeiron”), our largest shareholder, Florian Brand, our Chief Executive Officer, Srinivas Rao, our Chief Scientific Officer, and Lars Christian Wilde, Co-founder of COMPASS Pathways plc (“COMPASS”), with the aim of transforming the treatment of mental health disorders. This focus came out of direct experience with the trauma of mental health challenges such as depression and awareness of the potential solutions offered by unconventional approaches including psychedelic compounds. In addition to our founders, we have an experienced senior leadership team including Greg Weaver, our Chief Financial Officer, and Rolando Gutiérrez-Esteinou, our Chief Medical Officer. For more information regarding our people, see below under the section titled “Human Capital Management”.

Our Enabling Technologies
We believe our enabling technologies have the potential to support the development of our pipeline and be used as patient support tools. We currently have four enabling technologies housed at our atai companies: Introspect Digital Therapeutics, InnarisBio and Psyber, as well as IntelGenx Technologies, a strategic investment of ours. Introspect Digital Therapeutics is a digital therapeutics platform dedicated to improving patient outcomes through personalized care. InnarisBio is a formulation technology company developing a sol-gel based, intranasal excipient technology. Psyber is developing an EEG-based brain-computer interface technology for psychiatric use. IntelGenx Technologies is an oral thin film ("OTF") drug delivery system manufacturer that is currently developing an OTF formulation of Viridia's VLS-01. None of our existing programs were developed using these enabling technologies, and many of these technologies remain in early stage testing and development. We intend to use these enabling technologies to support the future development of our programs. For more information regarding our enabling technologies, see below under the section titled “Enabling Technologies”.

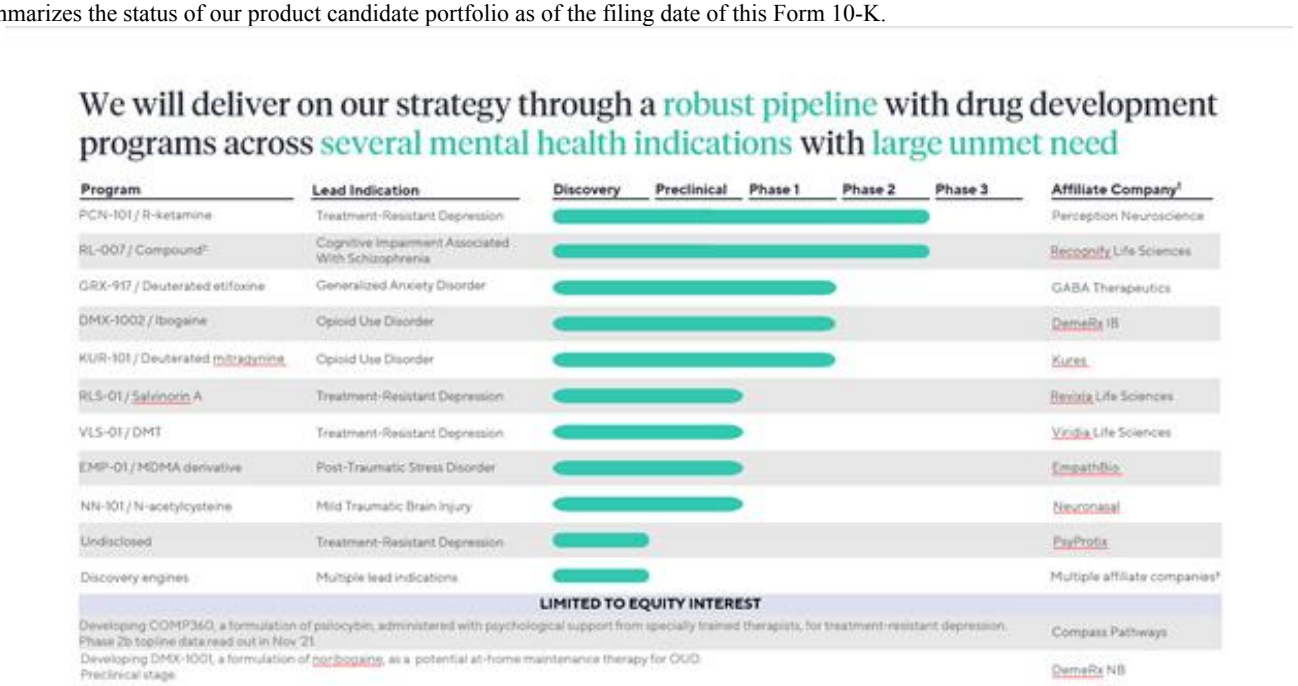
Our Drug Discovery Companies
We also believe in the development of innovative and scalable solutions to better meet patient needs and are conducting robust drug discovery through four subsidiary companies. EntheogeniX Biosciences uses an AI-enabled computational platform to create structurally differentiated molecules. PsyProtix, Inc. ("PsyProtix") is a discovery stage company that is developing compounds to treat specific subsets of treatment resistant depression ("TRD") patients that are characterized by mitochondrial dysfunction, and represents an important first step towards our goal of delivering biomarker-driven precision mental health. In December 2021 and January 2022, respectively, we announced the launch of two new companies to support this commitment in driving next-generation approaches in the treatment of mental health disorders, TryptageniX, Inc. (“TryptageniX”) and Invyxis, Inc. (“Invyxis”). These two companies’ approaches to drug discovery are highly complementary to that of EntheogeniX. TryptageniX will develop new chemical entities ("NCEs") through a unique bioprospecting

and synthetic biology approach and Invyxis brings proven medicinal chemistry and comprehensive biological evaluation capabilities to our discovery efforts. Expanding intellectual property has been essential to our strategy since inception, with key investments made to unlock NCEs. We have already made substantial progress in our drug discovery efforts to date, synthesizing and screening approximately 300 compounds and identifying novel scaffolds that display potential in targeting mental health disorders. For more information regarding our drug discovery companies, see below under the section titled "Drug Discovery Companies".

Our Programs

Our Emerging Clinical and Preclinical Programs

Our pipeline currently consists of therapeutic candidates across multiple neuropsychiatric indications including depression, cognitive impairment associated with schizophrenia ("CIAS"), opioid use disorders ("OUD"), anxiety, mild traumatic brain injury ("mTBI") 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 disorder, 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 filing date of this Form 10-K.



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

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

(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) Including EntheogeniX, TryptageniX, Invyxis

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

Perception Neuroscience: PCN-101 for TRD

- **Product concept**: PCN-101 is a parenteral formulation of R-ketamine, a glutamatergic modulator that is a component of racemic ketamine and is being developed as a rapid-acting antidepressant, with the potential to be an at-home non-dissociative alternative to S-ketamine (marketed as SPRAVATO).
- **Prior evidence in humans**: In a third-party clinical trial, another formulation of R-ketamine was observed to produce a rapid and durable response with limited dissociative side effects in patients with TRD. In September 2020, Perception Neuroscience completed a Phase 1 trial of PCN-101 supporting the advancement of PCN-101 into a Phase 2a proof-of-concept trial. In September 2021, the Phase 2a proof-of-concept trial of PCN-101 for TRD was initiated.

- **Upcoming milestones**: In December 2021, the FDA gave Investigational New Drug ("IND") clearance for the development of PCN-101 for the treatment of TRD. In September 2021, the Phase 2a proof-of-concept trial of PCN-101 for TRD was initiated. This randomized, double-blind, placebo-controlled Phase 2a proof-of-concept trial is designed to assess the efficacy, safety, dose response, and duration of response in patients with TRD. A topline data readout of this trial is expected by the end of 2022. We also anticipate results from a PCN-101 Phase 1 trial that bridges between the current intravenous formulation to a subcutaneous formulation to support at-home use, by the end of 2022.

Recognify Life Sciences: RL-007 for CIAS

- **Product concept**: RL-007, a cholinergic, glutamatergic and GABA-B receptor modulator, is an orally available compound that is thought to alter the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. We are developing this compound for the treatment of CIAS.
- **Prior evidence in humans**: In third-party studies, other formulations of this compound have been shown to effect a significant improvement in aspects of cognitive function in both experimental paradigms involving healthy subjects as well as in a Phase 2 trial in patients suffering from diabetic peripheral neuropathic pain. In April 2021, Recognify initiated a Phase 2 proof-of-mechanism study for RL-007 in 32 CIAS patients, after receiving IND clearance from the U.S. Food and Drug Administration to commence clinical trials for the treatment of CIAS. The study was designed to evaluate the effects of RL-007 on safety, tolerability, electroencephalogram-based biomarkers and cognition.
- **Recent advancements**: In December 2021, we announced positive biomarker data from the Phase 2a proof-of-mechanism study of RL-007 in CIAS patients. RL-007 was well tolerated and demonstrated a clinically meaningful behavioral pro-cognitive profile consistent with previous Phase 1 and 2 trials of this compound. Changes in quantitative electroencephalogram ("qEEG") consistent with a previous Phase 1 trial involving a scopolamine challenge were noted. These results support the progression of RL-007 to a double-blind, placebo-controlled Phase 2a proof-of-concept trial with the goal of demonstrating the pro-cognitive benefit of RL-007 in CIAS.
- **Upcoming milestones**: We anticipate the Phase 2a proof-of-concept trial to be initiated in the second half of 2022.

GABA: GRX-917 for GAD

- **Product concept**: GRX-917 is an oral formulation of a deuterated version of etifoxine, a compound that has a long history of prescription use in France and other countries for treating anxiety disorders. GRX-917 is designed to provide rapid anxiolytic activity with improved tolerability compared to current treatments for anxiety available in the United States.
- **Prior evidence in humans**: Etifoxine has been observed to have the rapid onset of anxiolytic activity of benzodiazepines without their sedating or addicting properties. Furthermore, etifoxine is not associated with abuse, dependence or respiratory depression and has been observed to have no significant impact on motor skills or cognition.
- **Recent advancements**: In June 2021, GABA initiated a Phase 1 single and multiple ascending dose trial of GRX-917. The ongoing Phase 1 trial is a randomized, double-blind, placebo-controlled study of the safety, tolerability and pharmacokinetics of single-ascending and multiple-ascending doses of GRX-917 administered orally to healthy volunteers.
- **Upcoming milestones**: Topline data for this trial is expected by mid-year 2022 and the initiation of a Phase 2a proof-of-concept trial is anticipated to follow in the second half of this year.

DemeRx IB: DMX-1002 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, that we are developing for the treatment of OUD.
- **Prior evidence in humans**: In third-party studies evaluating other formulations of ibogaine, significant reductions in opioid cravings were observed, both at discharge and at one month post treatment, and were associated with improved mood in patients with OUD.
- **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 opioid use disorder.
- **Upcoming milestones**: We expect safety data from the phase 1 element of the this trial in the second half of 2022.

Kures: KUR-101 for OUD

- **Product concept**: KUR-101 is an oral formulation of deuterated mitragynine being developed for the treatment of OUD. Mitragynine is a component of the leaves of kratom (Mitragnyna speciosaz).
- **Prior evidence in humans**: 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**: KUR-101 is a Phase 1 randomized, double-blind, two-part study of the safety, tolerability, pharmacokinetics, analgesic and respiratory effects of KUR-101 in healthy volunteers. Part 1 is a 5 cohort ascending dose design of a single dose of KUR-101. Part 2 is a three-period crossover design to compare the analgesic and respiratory effects of a single oral dose of KUR-101, a single oral dose of OxyNorm®, and a single oral dose of placebo in healthy male volunteers.
- **Upcoming milestones**: A Phase 1 single ascending dose trial to evaluate the maximum tolerable dosage was initiated, with first patient dosed in March and topline results expected in the second half of 2022.

Revixia Life Sciences: RLS-01 for TRD

- **Product concept**: RLS-01 is a formulation of SalA, a naturally occurring dissociative hallucinogenic compound, with pharmacology differentiated from that of psilocybin or DMT, being developed for the treatment of TRD and other indications.
- **Prior evidence in humans**: In a third-party study of another formulation of SalA, the effects of the compound were observed to be similar to those of psilocybin based upon functional brain imaging. We believe these data combined with anecdotal usage reports suggest that SalA may possess rapid-acting antidepressant properties.
- **Upcoming milestones**: RLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the second half of 2022.

Viridia Life Sciences: VLS-01 for TRD

- **Product concept**: VLS-01 is a formulation of DMT, the active moiety of the traditional, hallucinogenic drink ayahuasca. DMT is characterized by an intrinsically short duration of psychedelic effect with a serum half-life estimated at less than 10 minutes. VLS-01 is formulated to provide a psychedelic experience lasting 30 to 45 minutes, thus potentially allowing for a shorter clinic visit compared to many other psychedelic compounds that may require a patient to be monitored for four or more hours.
- **Prior evidence in humans**: Ayahuasca administration was shown to provide significant antidepressant effects compared with placebo at one, two and seven days after dosing in a double-blind, randomized, placebo-controlled third-party clinical trial in patients with TRD.
- **Upcoming milestones**: VLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the middle of 2022. The study will utilize buccal and IV formulations in healthy adult volunteers to assess the relative bioavailability of the buccal versus IV formulations, the safety and tolerability of VLS-01 administered by both routes, as well as pharmacodynamics using qEEG and other measures.

EmpathBio: EMP-01 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 for the potential to have an improved therapeutic index compared to racemic MDMA.
- **Prior evidence in humans**: 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 with 90 patients with severe PTSD, showed statistically significant reduction in PTSD symptoms in the MDMA-assisted psychotherapy group versus placebo.
- **Upcoming milestones**: EMP-01 is in preclinical development for PTSD with a Phase 1 trial expected to be initiated in the second half of 2022.

Neuronasal: NN-101 for mTBI

- **Product concept**: NN-101 is a novel intranasal formulation of NAC. NAC is believed to stimulate the synthesis of GSH, an endogenous antioxidant that plays a protective role in the pathogenesis of mTBI.
- **Prior evidence in humans**: An orally administered formulation of NAC was shown to increase the probability of mTBI symptom resolution at seven days in a third-party study conducted by the U.S. Army. Neuronasal has also completed a pilot study of NN-101 in nine healthy volunteers. In this pilot study, NN-101 was observed to be approximately 20 times and 100 times more brain-penetrant compared to IV and oral NAC, respectively, and was well tolerated.

Programs and Lead Indications

Depression Background

Depression 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, with depression rates reported to have increased threefold in the U.S. since the onset of the COVID-19 pandemic, for example. There are a wide range of available therapies for depression, including pharmacological treatments and psychological interventions, but these approaches have significant limitations for many patients, including slow and/or inadequate response, resulting in a significant unmet medical need.

Pharmacological treatment of depression is mostly based on drugs targeting the monoaminergic neurotransmitter system. Available therapies include antidepressants, such as SSRIs or SNRIs, and atypical antipsychotics, among others. In addition to efficacy limitations—as manifested by high rates of treatment resistance—these therapies are often associated with significant side effects, including weight gain, fatigue, nausea, apathy, sleep disturbances and sexual dysfunction, all of which can impair patient quality of life and impact compliance. It is estimated that global antidepressant sales could reach at least $8 billion by 2025.

We are initially focused on a subtype of depression referred to as TRD. TRD is a severe form of major depressive disorder, or MDD, comprising patients who inadequately respond to two or more depression treatments. Approximately one third of patients with MDD are diagnosed with TRD.

TRD is estimated to afflict approximately 100 million people globally and has greater economic and societal costs as compared to MDD patients that are not treatment resistant. TRD patients are often unable to perform daily tasks, are less productive at work and have higher rates of unemployment. These patients 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. In addition, direct medical costs for TRD patients are estimated to be two to three times higher than for MDD patients that are not treatment resistant, with an average of twice the number of inpatient visits and hospital stays that are over one-third longer. Furthermore, it has been found that the proportion of TRD patients that have attempted suicide may be as high as 30%, approximately a seven-fold increase compared with non-TRD MDD patients.

Given the limitations of existing therapeutic treatments, there continues to be high unmet need for antidepressants that provide greater efficacy, faster onset of effect, higher remission rates and improved tolerability. Most pharmacotherapies for depression use the same mechanism of action targeting the monoaminergic system and until recently, no novel mechanism of action had been approved for depression in several decades. S-ketamine (SPRAVATO) is a therapy for TRD approved in 2019 with a novel mechanism of action. S-ketamine (also referred to as esketamine) is one of the two enantiomers that constitute ketamine, an N-methyl-D-aspartic acid, or NMDA, receptor antagonist that has been used on-label for several decades for anesthesia induction, as well as off-label for depression and chronic pain. Ketamine consists of S-ketamine and R-ketamine in a 1:1 ratio.

S-ketamine addresses some of the limitations of current therapies with rapid onset of action and improved efficacy in treatment resistant patients. However, S-ketamine has several drawbacks, including the need for multiple administration sessions in a doctor's office involving a minimum two hour stay. The requirement for a supervised setting for administration is driven by both the dissociative side effects and abuse potential of S-ketamine. Thus, high unmet need still exists despite S-ketamine's approval.

Perception Neuroscience (PCN-101)

Perception Neuroscience is developing 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 nondissociative profile that has the potential to allow for at-home use and the possibility of combination treatment with SSRIs.

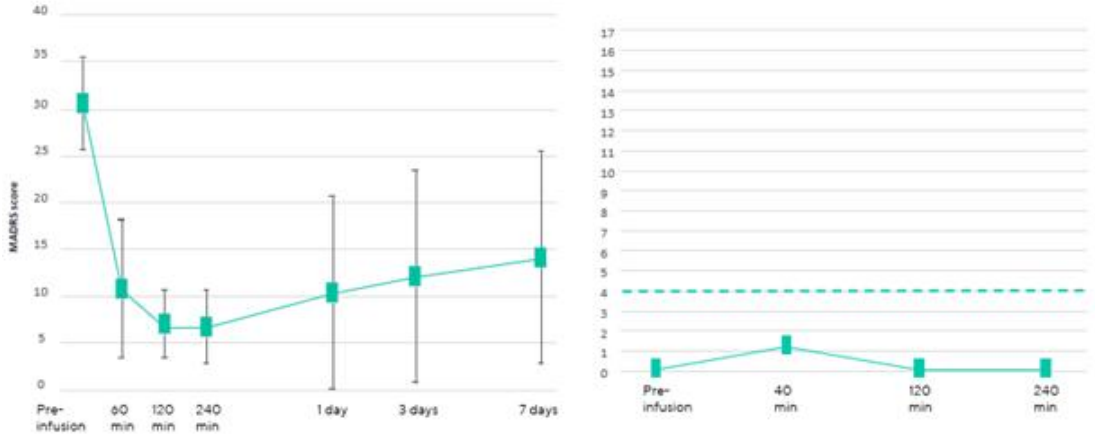
We believe PCN-101 has a potentially superior therapeutic profile versus S-ketamine based on the following observations in head-to-head third-party nonclinical studies of S-ketamine and other R-ketamine formulations:

- **Favorable tolerability profile.** R-ketamine was observed to have an approximately four-fold lower affinity for the NMDA receptor relative to S-ketamine in *in vitro* studies. Pharmacological activity at the NMDA receptor is thought to underlie some of the safety and tolerability issues associated with ketamine and S-ketamine, including the dissociative side effects.
- **Greater Potency.** R-ketamine was observed to be more potent compared to S-ketamine in multiple mouse models of depression.
- **Longer duration of effect.** R-ketamine led to longer duration of benefits compared to S-ketamine in multiple mouse models of depression.
- **Reduced abuse potential.** R-ketamine was observed to have no change in the conditional place preference, or CPP, score, a standard preclinical measure of abuse potential based on the ability of a drug to be associated with reward behavior. Conversely, administration of ketamine and S-ketamine in mice led to an increase in CPP score at doses efficacious in models of depression.

Prior Evidence in Humans
Across previously published, academic, third-party clinical studies involving other formulations, a total of 78 subjects have been administered R-ketamine in its purified form. Overall, less pronounced psychotomimetic and dissociative-like effects were reported with R-ketamine than with S-ketamine at equimolar doses.

Preliminary clinical evidence for the efficacy and tolerability of R-ketamine in patients with TRD was reported in the *European Archives of Psychiatry and Clinical Neuroscience* in 2020. This publication describes the results of a third-party, open-label trial conducted in seven TRD patients. A single IV infusion of R-ketamine (0.5 mg/kg) was reported to lead to a reduction in Montgomery-Åsberg Depression Rating Scale, or MADRS, a widely accepted scale for depression that has been used as a primary endpoint in pivotal trials of other depression treatments, within 60 minutes that was largely sustained through at least seven days, as shown in the figure below. The mean Clinician-Administered Dissociative States Scale, or CADSS, measures dissociative symptoms with a score of four or less being considered normal. At 40 minutes, the average CADSS score of R-ketamine was 1.1 (SD 1.7), whereas ketamine and S-ketamine reported mean CADSS scores of 18.2 and 14.9, respectively, in prior third-party clinical trials. It was observed that R-ketamine may produce rapid onset and sustained antidepressant effects in humans with a favorable tolerability profile and with dissociation being nearly absent.

A rapid decrease in depressive symptoms with limited dissociative side effects was seen in TRD patients after a single IV dose of R-ketamine



Note: Error bars represent standard deviation; MADRS = Montgomery Asberg Depression Rating Scale; CADSS = Clinician Administered Dissociative Symptom Scale; (n=7)

Phase 1 Clinical Data for PCN-101
In 2020, Perception Neuroscience conducted a Phase 1 trial of PCN-101 delivered by IV infusion in New Zealand. The study consisted of two parts. The objective of part one was to identify an acceptable tolerated dose of PCN-101 delivered by IV infusion in 48 healthy adults using a single ascending dose design. Safety endpoints included adverse events, vital signs, ECG parameters, blood hematology and chemistry, and clinical measures of sedation, dissociation, and psychotomimetic effects. Dose-related pharmacokinetics of PCN-101 were

also assessed. Part two was a double-blind, cross-over comparison of the relative safety and tolerability of the acceptable tolerated dose of PCN-101 identified in part one to S-ketamine, both delivered by IV infusion in ten healthy volunteers.

The Phase 1 data in healthy volunteers showed that PCN-101 was well tolerated at all doses up to 150 mg. Observed side effects were transient and consistent with expected effects seen with ketamine and S-ketamine. Importantly, the onset of dissociative and psychotomimetic effects was observed to occur at fourfold higher doses than the equimolar doses of S-ketamine. Qualitatively, the pattern of effects on dissociation and altered states of consciousness seemed similar to the effects seen with S-ketamine, albeit occurring at higher dose levels with PCN-101.

Phase 2 Clinical Trial of PCN-101
In September 2020, Perception Neuroscience completed the Phase 1 trial of PCN-101 supporting the advancement of PCN-101 into a Phase 2a proof-of-concept trial. In September 2021, Perception Neuroscience initiated the Phase 2a proof-of-concept trial of PCN-101 for TRD. This randomized, double-blind, placebo-controlled trial is designed to assess the efficacy, safety, dose response and duration of action in patients with TRD. A topline data readout of the Phase 2 proof-of-concept trial is expected by the end of 2022.

Patients will be randomized into three groups receiving a single infusion of either 30 mg of PCN-101, 60 mg of PCN-101 or placebo in clinic. The trial will aim to enroll approximately 93 patients in total (approximately 31 per cohort). PCN-101 at 30 mg and 60 mg dosages will be evaluated. In-clinic treatment will be preceded by a screening period and followed by two follow-up periods where clinical parameters will be assessed. The primary endpoint of the trial will be an assessment based on MADRS at 24 hours. Safety assessment measures will include CADSS, Modified Observer's Assessment of Alertness/Sedation Scale and Brief Psychiatric Rating Scale Positive Symptoms Subscale.

Other Clinical Trials of PCN-101
As we announced in January 2022, the FDA gave IND clearance to conduct a clinical DDI trial of PCN-101 for TRD. We also anticipate results from a Phase 1 trial that bridges between the current intravenous formulation to a subcutaneous formulation of PCN-101 to support at-home use by the end of 2022.

Viridia Life Sciences (VLS-01)
Viridia Life Sciences, our wholly owned subsidiary, is developing VLS-01, a synthetic form of DMT being developed in buccal and IV formulations initially for the treatment of TRD. DMT is the active psychedelic moiety in ayahuasca, a hallucinogenic drink made from a combination of leaves from several South American plants that has been shown to have antidepressant effects. Formulations of isolated or synthetic DMT that have been tested clinically to date include those that are inhaled or injected intravenously. As a result of the rapid absorption associated with these routes of administration and DMT's inherently fast metabolism, such approaches have been associated with poor tolerability and a very short duration of psychedelic effect.

Other psychedelic therapies, such a psilocybin, are promising treatments for depression, but their long duration of psychedelic effect requires a patient to be monitored for four to six hours, which may limit patient uptake and adherence. We are designing our buccal formulation of DMT to have the following characteristics:

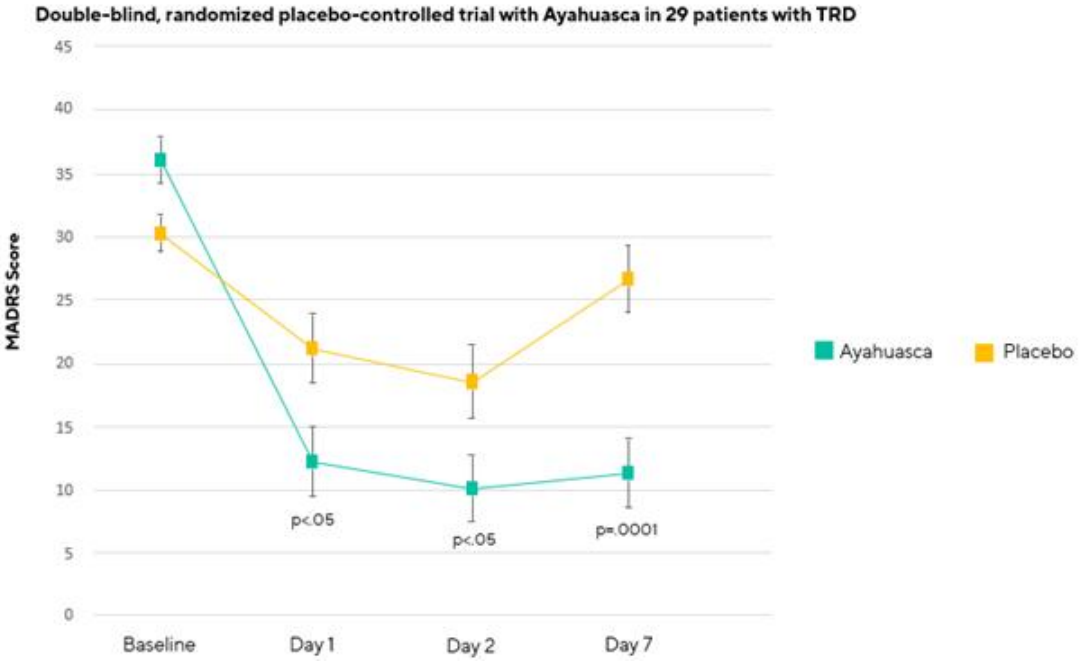
- **Improved PK Profile**. Our formulation is intended to have a longer absorption window while improving tolerability.

- **Short Duration of Psychedelic Effect**. Relative to many other psychedelic therapies, our formulation of DMT is designed to have a shorter duration of psychedelic effect at 30 to 45 minutes, which would allow for a shorter clinic visit compared to many other psychedelic compounds.

Viridia Life Sciences is working to develop a digital therapeutic, in collaboration with both Psyber and IntroSpect Digital Therapeutics, to provide contextual "(mind)set-and-setting" prior to dosing, as well as behavioral activation therapy, group therapy, and patient monitoring post dosing.

Prior Evidence in Humans
In a double-blind randomized placebo-controlled third-party trial in 29 patients with TRD, statistically significant antidepressant effects of ayahuasca given orally were observed when compared with placebo, based on changes in depression severity measured with the MADRS at baseline and at one, two and seven days after dosing. The antidepressant effects of ayahuasca were observed at each time point compared to placebo.

An oral dose of ayahuasca led to rapid and sustained decrease in mean MADRS relative to placebo



Note: Error bars represent standard error of the mean; MADRS = Montgomery Asberg Depression Rating Scale; (n=29)
*denotes p-value <0.05.
***denotes p-value <0.0001.

Planned Phase 1 Clinical Trial of VLS-01
VLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the middle of 2022. The study will utilize buccal and IV formulations in healthy adult volunteers to assess the relative bioavailability of the buccal versus IV formulations, the safety and tolerability of VLS-01 administered by both routes, as well as pharmacodynamics using qEEG and other measures.

Revixia Life Sciences (RLS-01)
Revixia Life Sciences, our wholly owned subsidiary, is developing RLS-01, a formulation of Salvinorin A, or SalA, for the treatment of TRD. SalA is a unique, non-orally bioavailable, non-nitrogenous agonist of the kappa-opioid receptor, or KOR, with potential use in treating TRD, SUD and pain. The compound is naturally occurring and is derived from the Salvia divinorum plant. SalA's non-serotonergic mechanism of action (unlike psilocybin and DMT) may allow for combination treatment with SSRIs and other therapies that share a serotonergic mechanism of action.

Revixia Life Sciences is working to develop a digital therapeutic, in collaboration with both Psyber and IntroSpect Digital Therapeutics, to provide contextual "(mind)set-and-setting" prior to SalA dosing, behavioral activation therapy, group therapy, and patient monitoring.

Prior Evidence in Humans
A double-blind, placebo-controlled, randomized third-party study of 30 participants evaluated the acute differences in behavioral and psychological effects of enhanced, smoked S. divinorum leaf (containing approximately 40 µg/mg SalA per dried leaf) relative to a placebo compound (containing a presumed non-psychoactive dose of approximately 4 µg/mg SalA per dried leaf) and found that all six Hallucinogen Rating Scale, or HRS, clusters were significantly elevated ($p<0.05$) for participants given the active S. divinorum leaf, consistent with a hallucinogenic effect. No significant adverse events were observed or reported by the participants. Additionally, in a third-party study of another formulation of SalA, the effects of the compound were observed to be similar to those of psilocybin based upon functional brain imaging.

Planned Phase 1 Clinical Trial of RLS-01
RLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the second half of 2022.

Cognitive Impairment Associated with Schizophrenia (CIAS) Background
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.

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. People with schizophrenia are two to three times more likely to die early than the general population, with suicide being the main contributor in the early course of disease and cardiovascular disease being the main contributor in later years.

Schizophrenia is considered more than a psychotic disorder. Patients are often limited in their ability to distinguish facial expressions, voice tone or pitch, and have difficulty with tasks related to learning, memory and mental processing. Nearly every schizophrenia patient is affected by CIAS, limiting both social and non-social cognitive functions.

The annual U.S. economic burden due to schizophrenia is estimated to exceed $155 billion. People living with schizophrenia often experience a reduced quality of life and are more likely to be homeless, unemployed or living in poverty compared with the general population. While antipsychotics are most commonly used to treat the psychotic symptoms of schizophrenia, these medications fail to address the cognitive and negative symptoms and are often associated with severe dose limiting effects. It is estimated that global sales of antipsychotics could reach $13 billion or more by 2025. To date, there are no pharmacological treatments approved for CIAS.

Recognify Life Sciences (RL-007)
Recognify is developing RL-007, an orally available compound that is thought to modulate the excitatory/inhibitory balance to improve learning and memory, supporting potential use in CIAS patients. RL-007 is thought to impact the cholinergic, NMDA and gamma aminobutyric acid type B, or GABAB, receptor systems. We have observed pro-cognitive effects of RL-007 in animal models and in clinical trials, and RL-007 is thought to act directly on brain regions involved with learning and memory processes. In contrast to other compounds that modulate GABAB receptors, we observed RL-007 to be non-sedating in preclinical studies at doses approximately 1000 times greater than its effective dose. The non-sedating effects of the compound were equally observed in subsequent clinical studies.

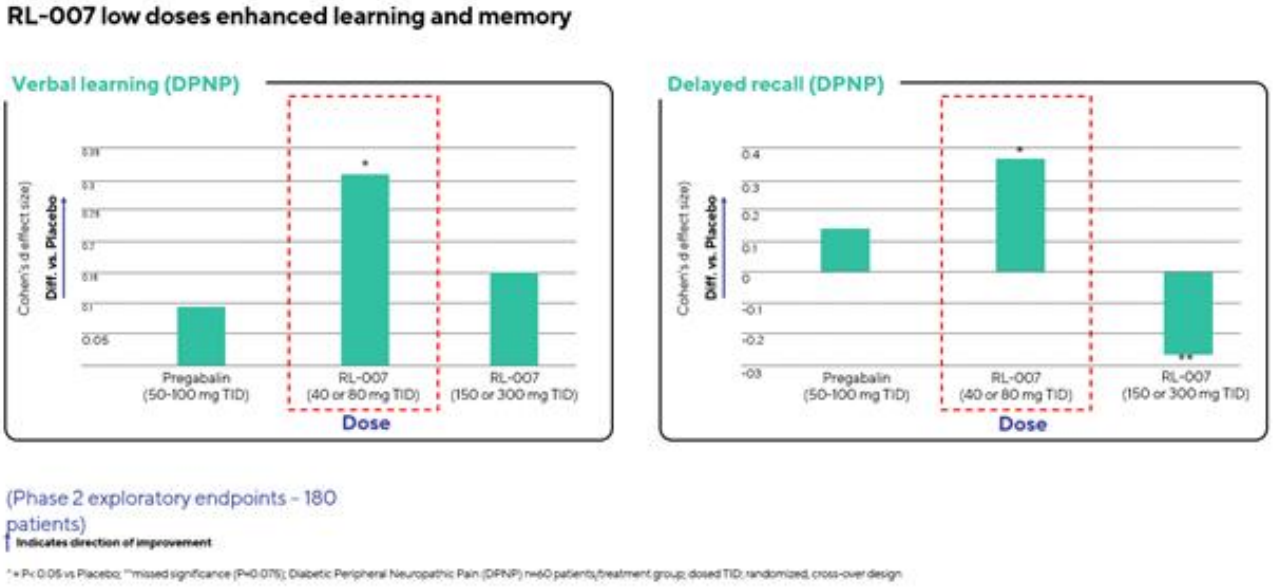
Prior Evidence in Humans
RL-007 was previously in development for the treatment of neuropathic pain and has been tested in nine Phase 1 and Phase 2 clinical trials. The compound has been assessed in over 500 subjects and no drug-related serious adverse events were observed. Pro-cognitive effects of RL-007 were observed in three prior third-party clinical trials, including two Phase 1 trials and one Phase 2 trial.

In a clinical pharmacology trial in healthy volunteers, RL-007 at doses of 30 mg, 150 mg and 750 mg, was observed to protect against the memory impairing effects of a single dose of scopolamine (0.5 mg). At the lowest dose tested, RL-007 was observed to protect against scopolamine-induced impairment of episodic memory as shown by an improvement in the composite score of ‘Quality of Episodic Secondary Memory’ during cognitive testing at 1.5 and 3 hours following the dose. This improvement was primarily due to the effects on the delayed word recall task. Further evidence of the protective effect of RL-007 at the 30 mg dose was observed against scopolamine-induced impairment of the ability to sustain attention, as indicated by an improvement in the composite score ‘Continuity of Attention’ at 1.5 hours following the dose. This improvement was primarily due to the effects of RL-007 on the subject performance on the Digit Vigilance False Alarms Test. At later time points (4.5 and 10 hours following the dose), a delayed recovery from the effects of scopolamine was seen on several measures, primarily in the cohorts receiving the higher doses of RL-007.

A randomized double-blind, placebo and active-controlled Phase 2a crossover trial of RL-007 was conducted in 181 patients with diabetic neuropathy by a third party. No improvements in pain scores were associated 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.

Verbal learning includes immediate and delayed word recall exercises by using the International Shopping List Task, or ISLT, method and delivered by Cogstate’s computerized assessment system. The below graph from a third party study illustrates the improved verbal learning ability of the low dose RL-007 (FSV7-007) group (40 or 80mg three times a day (TID)), compared to pregabalin and high dose RL-007 (FSV-007).

RL-007 low doses enhanced verbal learning and memory



Note: RL-007 (FSV7-007) is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propan-1-one(L)-(+) tartrate salt; TID denotes 3x/day dosing; (n=181)

Phase 2a Clinical Trial of RL-007

In December 2021, we announced positive biomarker data from the Phase 2a proof-of-mechanism study of RL-007 in CIAS patients. RL-007 was well tolerated and demonstrated a clinically meaningful behavioral pro-cognitive profile consistent with previous Phase 1 and 2 trials of this compound. Changes in quantitative electroencephalogram ("qEEG") consistent with a previous Phase 1 trial involving a scopolamine challenge were noted. These results support the progression of RL-007 to a double-blind, placebo-controlled Phase 2a proof-of-concept trial in CIAS, which is anticipated to be initiated in the second half of 2022.

Substance Use Disorder Background

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 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.

Buprenorphine, methadone and naltrexone are used as maintenance therapy with the primary goal of preventing relapse while naloxone is used as rescue therapy for opioid overdose. Access to treatments such as buprenorphine and methadone is limited by their treatment regimens and inherent risks of abuse, placing significant requirements and regulations on practitioners. In addition to these limitations, current treatment options are not highly effective; approximately 75% of patients undergoing OUD therapy experience relapse within one year of treatment. For abuse of other substances, such as cocaine or methamphetamine, no pharmacological agents have been approved.
Despite the limitations of current treatment options, the worldwide market for OUD therapies totaled $1.9 billion in 2018, the vast majority of which came from the United States. Furthermore, due to the significant increase in opioid use and the heightened response to the opioid crisis, the worldwide market for opioid abuse therapies is projected to grow by over 10% per year, signaling significant need for new treatment options.

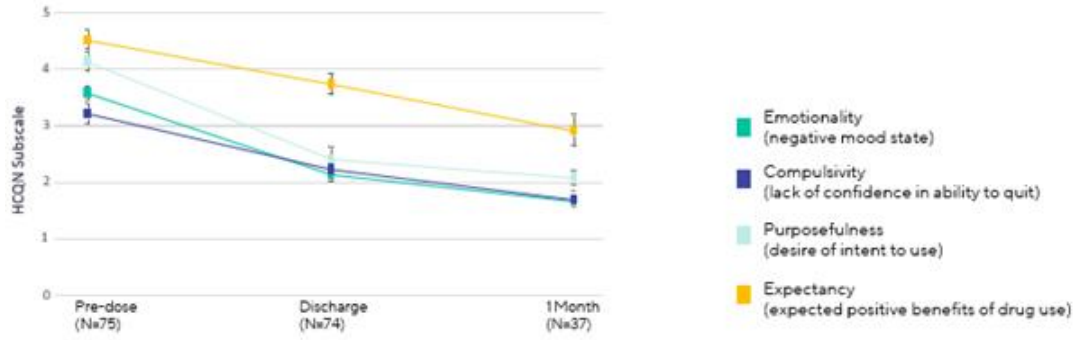
DemeRx IB (DMX-1002)
DemeRx IB is developing DMX-1002, a formulation of ibogaine, initially for the treatment of OUD. Ibogaine is a naturally occurring psychedelic product isolated from a West African shrub. Ibogaine was marketed in France as an antidepressant (known as Lambarere) from 1939 to 1970, though it is currently no longer marketed as a therapeutic anywhere in the world. We believe DMX-1002 has the potential to become a disease-modifying treatment for OUD, meaning that a single therapeutic dose administered in a monitored setting could potentially provide reduced opioid use, sustained for a period of at least three months, in previously opioid dependent patients.

Prior Evidence in Humans
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).

Administration of single doses of ibogaine led to significant reductions in standard instruments used to measure drug craving



Note: Results depict scores on HCQN subscale (Heroin Craving Questionnaire); Error bars represent standard error of the mean.

Phase 1/2 Clinical Trial of DMX-1002
The Phase 1/2 clinical trial of ibogaine HCl (DMX-1002) is being tested in an ongoing Phase 1/2 trial designed to evaluate its safety, tolerability, pharmacokinetics, and efficacy in recreational drug users and healthy volunteers, to help inform future studies in patients with opioid use disorder. The enrollment of approximately 80 patients with OUD are to be treated with DMX-1002 (N=~40) or placebo (N=~40). The primary endpoint of the Phase 2 portion of the trial will be abstinence or harm reductionurine-confirmed relapse out to 90 days post administration of ibogaine. We expect safety data from the phase 1 element of the this trial in the second half of 2022.

Kures (KUR-101)
Kures is developing KUR-101 for the treatment of OUD. KUR-101 is a deuterated version of mitragynine, the major alkaloid in kratom that is a relatively low-potency mu-opioid receptor, or MOR, agonist. KUR-101 is a semisynthetically produced drug substance designed to improve the safety profile and potential effectiveness of mitragynine. In results from our preclinical studies carried out to date, KUR-101 has shown dose-dependent analgesic effect without inducing significant respiratory depression at therapeutic doses in animal models.

Prior Evidence in Humans
Consumption of the leaves of kratom tree (Mitragyna speciosa, Rubiaceae family) has a long history in Southeast Asia. Whole leaves and their extracts have been consumed for their psychoactive properties or to self-manage or self-treat a broad range of conditions or ailments including pain and opioid withdrawal symptoms. Typically, only the kratom leaves are consumed, including chewing the whole leaves, ingesting or smoking dried and pulverized leaves or drinking water extracts based on steeping or boiling of the leaf material. In Malaysia, kratom is primarily consumed as a decoction, where the leaves are boiled for several hours and the resulting liquid is consumed several times throughout the day.

A randomized, placebo-controlled, double-blind third-party study of kratom extracts in 26 male subjects evaluated pain tolerance in a cold pressor task as time (in seconds) between pain onset and hand withdrawal from the ice bath. Pain tolerance significantly increased 1 hour after kratom ingestion in the experimental group ($p=0.007$) but was unchanged in the placebo group.

Phase 1 Clinical Trial of KUR-101
KUR-101-101 is a Phase 1 randomized, double-blind, two-part study of the safety, tolerability, pharmacokinetics, analgesic and respiratory effects of KUR-101 in healthy volunteers. Part 1 is a 5 cohort ascending dose design of a single dose of KUR-101. Part 2 is a three-period crossover design to compare the analgesic and respiratory effects of a single oral dose of KUR-101, a single oral dose of OxyNorm®, and a single oral dose of placebo in healthy male volunteers. A Phase 1 single ascending dose trial to evaluate the maximum tolerable dosage was initiated, with first patient dosed in March 2022 and topline results expected in the second half of 2022.

Anxiety Disorder Background
Anxiety is considered a common aspect of life, but anxiety disorders develop when feelings of apprehension and unease persist over an extended period and potentially worsen over time. Anxiety disorders can present with a range of symptoms and may impact personal health as well as both social and professional interactions. Furthermore, it is common for those suffering with an anxiety disorder to also have co-occurring mental health disorders or physical illness, which can compound symptoms and complicate recovery. For example, it is estimated that half of patients diagnosed with depression also suffer from an anxiety disorder.

There are several types of anxiety disorders, including generalized anxiety disorder, or GAD, social anxiety disorder and panic disorder, which are distinct but share common symptoms. In aggregate, anxiety disorders are considered to be the most common mental illness in the United States, affecting approximately 40 million adults, or 18% of the population. Furthermore, the total annual cost of anxiety disorders in the United States is estimated to be over $42 billion, of which more than 75% can be attributed to morbidity, mortality, lost productivity and other indirect costs.

We are initially focused on GAD, which is characterized as excessive, prolonged and difficult to control anxiety and stress that can impact normal life activities. GAD symptoms can vary, but may include behavioral traits such as unwarranted or disproportional anxiety, difficulty handling uncertainty and indecisiveness, in addition to physical signs such as fatigue and trembling. GAD is diagnosed when an individual finds it challenging to control anxiety on more days than not for at least a six-month period and has three or more symptoms. GAD can emerge gradually and most frequently manifests between childhood and middle age. Within the United States, GAD affects almost seven million adults.

Anxiety disorders are generally treated with medication, psychotherapy or both. First line therapy often involves use of antidepressants including SSRIs, such as paroxetine, sertraline and citalopram. SSRIs work by increasing levels of serotonin in the brain, but they typically have a slow onset of action, with treatment required 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 also associated with the development of tolerance and dependence, making discontinuing such medications challenging for most patients. Finally, benzodiazepines have been noted to exacerbate the respiratory depression associated with opioids, thus contributing to the mortality associated with OUD.

GABA Therapeutics (GRX-917)

GABA Therapeutics is developing GRX-917, a deuterated version of etifoxine, initially for the treatment of GAD. Etifoxine is a drug that has a long history of use in France and many other countries (though not the United States) for treating anxiety disorders and has a strong safety record. A review of over 14 million prescriptions between 2000 and 2012 by Agence Nationale de Sécurité du Médicament et des Produits de Santé, or ANSM, in France found no cases of abuse, misuse or pharmacodependence. Etifoxine has the rapid onset of anxiolytic activity of benzodiazepines without their sedating, addicting, or respiratory significant impact on motor skills or cognition.

Etifoxine was originally developed in the 1960s and approved in France in 1979. At the time, its rapid onset activity and non-sedating properties led it to be classified as a weakened atypical benzodiazepine-like drug. Only recently was it determined that etifoxine exerts its activity through two mechanisms unrelated to those of benzodiazepines. Etifoxine has been shown to be a low potency, positive allosteric activator of gamma aminobutyric acid type A, or GABAA, receptors, binding to a site that is independent of that recognized by benzodiazepines. A second activity of etifoxine has more recently been described that may play a more prominent role in the agent's anxiolytic activity. Specifically, etifoxine has been shown to activate the translocator protein, or TSPO, a transmembrane protein located on the outer mitochondria membrane. TSPO activation leads to increased synthesis of neuroactive steroids, including allopregnanolone and pregnanolone, that in turn function as positive allosteric modulators of GABAA receptors. Studies have shown that subsets of individuals with disorders such as depression and anxiety have lower levels of endogenous neuroactive steroids in their cerebrospinal fluid compared to healthy individuals. An IV formulation of allopregnanolone (Zulresso) was recently approved by the FDA for the treatment of post-partum depression. At high doses, direct administration of allopregnanolone can result in loss of consciousness and other adverse effects. It is thought that the ability of etifoxine to work with the body to increase levels of endogenous neurosteroids and raise GABAA activity in specific brain regions leads to a more natural physiological response and improved safety and tolerability.

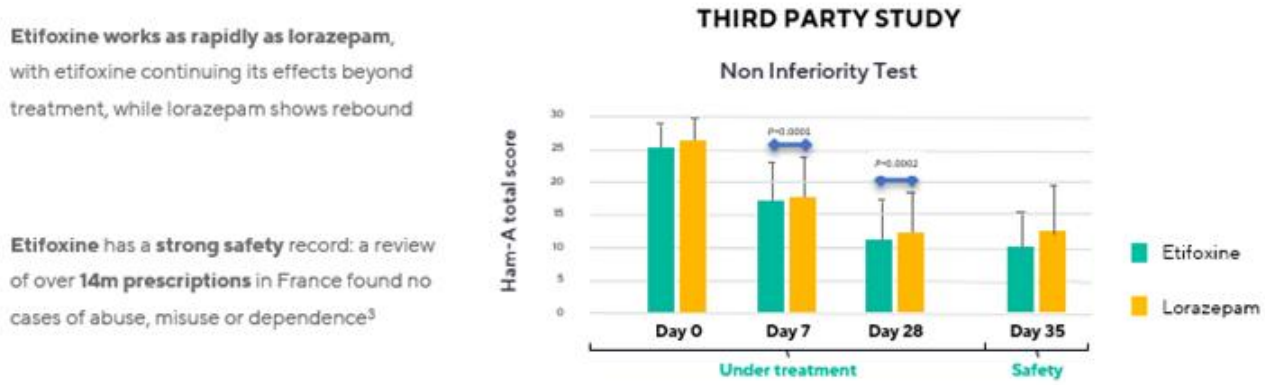
GRX-917 is designed, through the process of deuteration, to address certain limitations of etifoxine while maintaining its pharmacological benefits. Specifically, etifoxine has a half-life of approximately four hours in adults and is typically dosed three times per day. Deuterated etifoxine has the potential to extend the half-life and thus be dosed less frequently.

We believe the anticipated clinical profile of GRX-917 is beneficial compared to certain existing treatments, particularly SSRIs and benzodiazepines. GRX-917 is being designed to have rapid efficacy (expected in the first day of use) like a benzodiazepine but without the well documented safety concerns associated with such compounds, including sedation, cognitive impairments and abuse liability, which make chronic use undesirable. GRX-917 is also being designed to be well-suited for chronic use, like an SSRI, but without such compound's slow onset of activity and side effects, which may include sexual dysfunction, impaired sleep and gastrointestinal discomfort.

Prior Evidence in Humans

Etifoxine has been shown to have comparable time to onset and efficacy to several benzodiazepines (like Ativan, Xanax, and Klonopin) in head-to-head clinical trials but with fewer adverse effects. For example, etifoxine was non-inferior to Ativan (lorazepam) in a double-blind randomized parallel study conducted by a third-party in subjects with adjustment disorders with anxiety, or ADWA. In the study, 191 ADWA patients were assigned to receive etifoxine (50 mg TID) or lorazepam (0.5-0.5-1 mg per day) for 28 days. Efficacy was evaluated on days 7 and 28 of the treatment with the Hamilton Rating Scale for Anxiety, or HAM-A, score on Day 28 adjusted to Day 0 the main efficacy assessment criterion. The anxiolytic effect of etifoxine was found to be non-inferior to that of lorazepam (HAM-A score decrease: 54.6% vs 52.3%, respectively, p=0.0006). However, more etifoxine recipients responded to the treatment (HAM-A score decreased by 50%, p=0.03) and more etifoxine patients improved markedly (p=0.03) and had a marked therapeutic effect without side effects as assessed by Clinical Global Impression scale, (p=0.04). Furthermore, one week after stopping treatment, fewer patients taking etifoxine experienced a rebound of anxiety, compared to lorazepam (one and eight, respectively, p=0.034).

Double-blind controlled study comparing etifoxine to lorazepam monotherapy demonstrated non-inferiority in anxiolytic effects



Note: HAM-A = Hamilton Anxiety Rating Scale; (n=191)

Etifoxine has a strong safety record. A review of over 14 million prescriptions between 2000 and 2012 by Agence Nationale de Sécurité du Médicament et des Produits de Santé, or ANSM, in France found no cases of abuse, misuse or pharmacodependence. Moreover, no tolerance, withdrawal or rebound effects were reported. The overall rate of adverse drug reactions, or ADRs, was 21 per million in 2011 (ADR range was 13-50 per million prescriptions per year for 2002-2011) with very rare reports of serious adverse events. Over half of the serious adverse events were for dermatological and hypersensitivity reactions.

Phase 1 Clinical Trial of GRX-917
In June 2021, GABA initiated a Phase 1 single and multiple ascending dose trial of GRX-917. The ongoing Phase 1 trial is a randomized, double-blind, placebo-controlled study of the safety, tolerability and pharmacokinetics of single-ascending and multiple-ascending doses of GRX-917 administered orally to healthy volunteers. Topline data for this trial is expected by mid-year 2022 and the initiation of a Phase 2a proof-of-concept trial is anticipated to follow in the second half of this year.

Traumatic Brain Injury Overview
Traumatic brain injury, or TBI, typically occurs when a sudden force impacts the head, resulting in damage and functional impairment of the brain. Injuries range in severity, from mild, characterized by a brief change in mental status or consciousness, to severe, involving an extended period of unconsciousness or amnesia. In the United States, an estimated 1.7 million people sustain a TBI annually and there are approximately 57,000 annual TBI-related deaths. Nearly 5.3 million people in the United States live with TBI-related disabilities, and 70% to 90% of patients being treated for TBI continue to exhibit prolonged neurocognitive dysfunctions.

Mild TBI, or mTBI, accounts for 70% to 80% of all reported TBIs, but the prevalence may be even higher, as many cases often do not receive medical attention. Symptoms of mTBI may include headaches, fatigue, depression, irritability and impaired cognitive function and may persist for many years, negatively affecting quality of life. In addition, mTBI can lead to increased risk of affective mood disorders such as MDD, PTSD and other psychiatric and nonpsychiatric disorders.

To date, there are no pharmacological treatments approved for mTBI, and there are limited assets in development. Patients with mTBI are often told to avoid mentally strenuous activities to allow their brains to rest, but a lack of treatment may lead to increased risk of affective disorders and long-term cognitive impairment, underscoring the need for new effective treatments.

Post-Traumatic Stress Disorder Background
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.

EmpathBio (EMP-01)

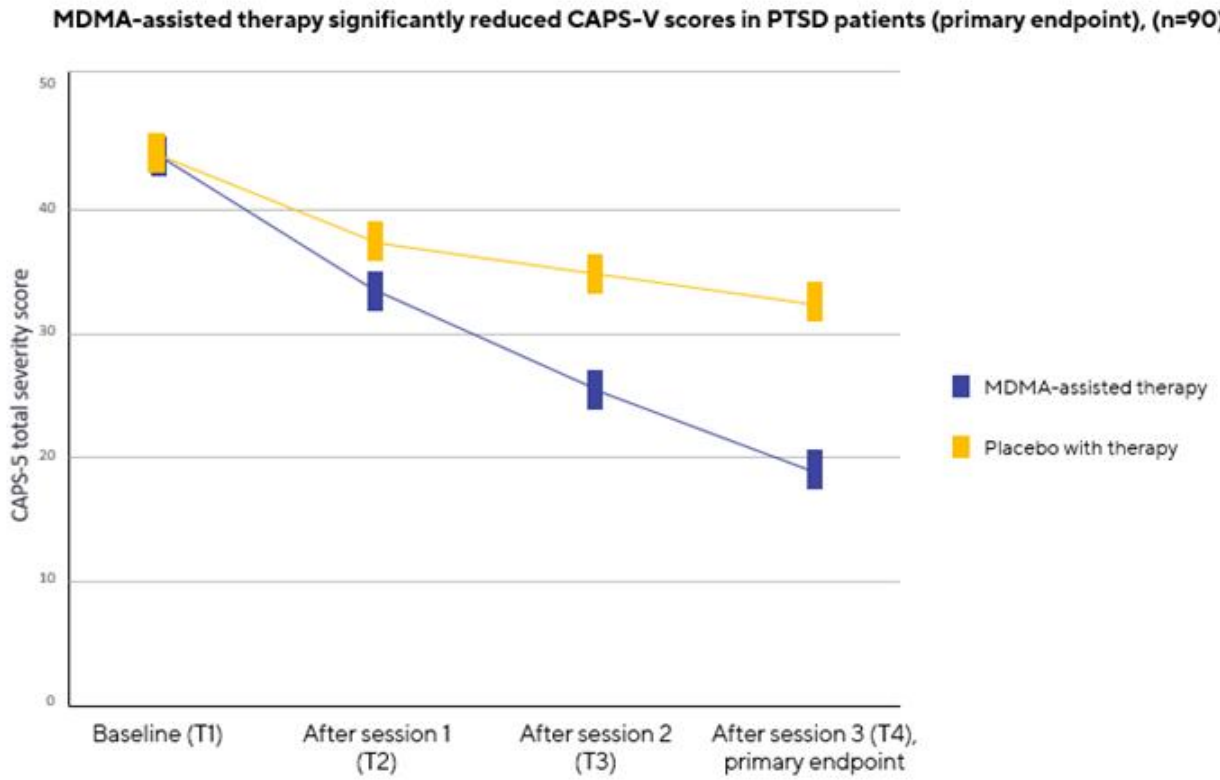
EmpathBio Inc., our wholly owned subsidiary, is developing EMP-01, a derivative of MDMA, the latter also known as ecstasy, for the treatment of PTSD. MDMA is considered the prototype of a class of compounds called entactogens, the primary characteristic of which is a capacity to increase feelings of love, empathy and closeness towards others. Racemic MDMA has a complex pharmacological profile that is dominated by effects as both a monoamine releaser and reuptake inhibitor. Its prominent effects on serotonin (5-HT) differentiate it from amphetamine and methamphetamine, both of which primarily act on the dopamine (DA) and norepinephrine (NE) pathways. EmpathBio is working to develop a digital therapeutic, in collaboration with both Psyber and IntroSpect Digital Therapeutics, to provide contextual "(mind)set-and-setting" prior to SalA dosing, behavioral activation therapy, group therapy, and patient monitoring.

Prior Evidence in Humans

A pooled analysis of six Phase 2 randomized, controlled third-party trials of MDMA-assisted psychotherapy for the treatment of PTSD revealed a statistically significant reduction in Clinician-Administered PTSD Scale for DSM-IV, or CAPS-IV, scores. The between-group Cohen's d effect size was 0.8, indicating a substantial treatment effect. After two experimental sessions with 75-125 mg of MDMA, 54.2% of active-dose participants (n=72) no longer met PTSD diagnostic criteria, compared with 22.6% of control participants (n=31) who received 0-40mg of MDMA.

In a third party randomized, double-blind, placebo-controlled phase 3 study (n=90), published in May 2021, MDMA-assisted psychotherapy was shown to statistically significantly reduce PTSD symptoms in severe PTSD patients, compared to therapy alone. Participants were given either MDMA or placebo at three sessions approximately 4-weeks apart in a controlled clinical environment and in the presence of a trained therapy team. MDMA was found to induce a statistically significant attenuation in PTSD symptomatology compared to placebo, as assessed by the CAPS-V total severity score ($P < 0.0001$, $d = 0.91$) and the Sheehan Disability Scale, or SDS, total score ($P = 0.0116$, $d = 0.43$).

MDMA-assisted therapy significantly reduced CAPS-V scores in PTSD patients (primary endpoint)



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)

Planned Phase 1 Clinical Trial of EMP-01
EMP-01 is in preclinical development for PTSD with a Phase 1 trial expected to be initiated in the second half of 2022.

Enabling Technologies
We have four enabling technologies that we believe have the potential to support the development of our pipeline and be used as patient support tools. Our enabling technologies housed at our atai companies include: Introspect Digital Therapeutics, InnarisBio, Psyber and IntelGenx Technologies. Introspect Digital Therapeutics, a wholly owned subsidiary we launched in June 2020, is a digital therapeutics platform dedicated to improving patient outcomes through personalized care. InnarisBio, a majority owned subsidiary we launched in March 2021, is a formulation technology company developing a sol-gel based, intranasal excipient technology. In February 2021, we acquired a majority interest in Psyber, which is developing an EEG-based brain-computer interface technology for psychiatric use. In May 2021, we acquired a minority interest in IntelGenx Technologies, an OTF drug delivery system manufacturer that is currently developing an OTF formulation of Viridia's VLS-01. None of our existing programs were developed using these enabling technologies, and many of these technologies remain in early stage testing and development. We intend to use these enabling technologies to support the future development of our programs, as further described below.

- **IntroSpect Digital Therapeutics** is a wholly owned digital therapeutics platform dedicated to improving patient outcomes through personalized care. We believe capabilities such as symptom tracking, mobile application-based therapy (e.g., behavioral activation therapy) and remote monitoring, have the potential to improve patient outcomes as has been observed with other, similar therapies, such as Pear Therapeutics' reSET-O. The FDA has also recently expressed support for digital health initiatives through its Digital Health Innovation Action Plan. We intend to incorporate digital therapeutics into the design of clinical trials for several of our programs, including DemeRx IB and Viridia. In September 2021, we announced the initiation of a usability study of Introspect's digital therapeutic ("DTx") app technology in support of standard of care ketamine therapy for patients with TRD in collaboration with Kadima Neuropsychiatry. Introspect's DTx app approach to supported treatment in mental health are integrated across 3 cohorts. Cohort 1 and Cohort 2, each successfully completed, focused on user acceptability and examined the introduction of therapeutic content via the app, respectively; and Cohort 3, which is ongoing, is assessing (mind)set and setting of treatment.

- **InnarisBio** is a joint venture with UniQuest, the commercialization and technology transfer company of the University of Queensland, Australia, with atai owning 82% as of December 31, 2021. InnarisBio is dedicated to developing a sol-gel based, intranasal excipient technology to facilitate nose-to-brain, or N2B, delivery of platform compounds, starting with Salvinorin A and with potential plans to expand to additional active pharmaceutical ingredients, or APIs. InnarisBio's non-invasive, N2B delivery technology is designed to avoid systemic circulation and first-pass metabolism, both factors that may reduce safety risks, depending upon the API. Potential additional advantages include increased patient compliance, ease of administration and rapid onset of action.

- **Psyber** is a majority owned subsidiary, with atai owning 75% as of December 31, 2021. Psyber is developing interventions that use brain computer interface-based technology to induce rapid behavioral change through biofeedback. Beneficial effects of BCI-based approaches have been observed on stress reduction, attention and emotional modulation in humans. Our initial application of this technology platform is to enhance both "(mind)set and setting" prior to and during psychedelic dosing. We intend to co-develop this technology with our psychedelic therapies and IntroSpect Digital Therapeutics' mobile application and anticipate a prototype at the end of 2022.

- **IntelGenx Technologies** is an OTF manufacturer based in Montreal, Canada with a Canadian Schedule 1 license, allowing it to develop re-formulations of scheduled compounds. Currently, IntelGenx is developing an additional OTF formulation of Viridia's VLS-01. OTF formulations are designed to enable delivery of therapeutics through oromucosal absorption, thereby avoiding the stomach and first-pass metabolism and allowing for non-invasive delivery of non-orally bioavailable therapeutics. In May 2021, we acquired a 25% interest in IntelGenx as part of a strategic partnership in which we and IntelGenx cooperate to conduct research and development projects. As part of the agreement, atai acquired additional warrants and received the right to purchase additional shares and warrants, leading to a potential path to majority ownership. So long as we maintain certain levels of our initial equity ownership in IntelGenx, IntelGenx will work exclusively with us in the field of compounds for the prevention or treatment of mental health diseases or disorders and compounds that have psychedelic, entactogenic and/or oneirophrenic properties, but excluding certain specific compounds and veterinary applications.

Drug Discovery Companies
We have four drug discovery companies that we believe have the potential to support our commitment in driving next-generation approaches in the treatment of mental health disorders to better meet patient needs. Our drug discovery companies include EntheogeniX Biosciences, PsyProtix, TryptageniX and Invyxis. In November 2019, we acquired a majority interest in EntheogeniX Biosciences, a controlled variable interest entity, is an AI-enabled computational platform to create structurally differentiated molecules. PsyProtix, a majority owned subsidiary we launched in February 2021, is a discovery stage company that is developing compounds to treat specific

subsets of TRD patients that are characterized by mitochondrial dysfunction. In December 2021, we announced the launch of TryptageniX, a new platform company that will specialize in both the discovery of NCEs for our pipeline through a unique bioprospecting and synthetic biology approach of our naturally derived development candidates. More recently, in January 2022, we announced the launch of Invyxis, a new, wholly owned platform company committed to developing new chemical entities NCEs and to further pioneering next-generation mental health treatments bringing proven medicinal chemistry and comprehensive biological evaluation capabilities to our discovery efforts. These approaches are expected to further strengthen our already robust intellectual property portfolio spanning psychedelic and non-psychedelic compounds. We intend to use these drug discovery companies to support the future development of our programs, as further described below.

- **EntheogeniX Biosciences** is a discovery stage joint venture with Cyclica, with atai owning 80% as of December 31, 2021, dedicated to developing the next generation of innovative mental health drugs. EntheogeniX leverages Cyclica's AI-enabled computational biophysics platforms—Ligand Design and Ligand Express—to accelerate drug discovery. We believe EntheogeniX has the potential to be a drug discovery engine for atai, supporting the next generation of novel compounds. We anticipate EntheogeniX identifying a lead product candidate in the second half of 2022.
- **PsyProtix** is a joint venture with Chymia, a spinout of Duke University, with atai owning 75% as of December 31, 2021. PsyProtix is a discovery stage company that is targeting subsets of TRD patients that are characterized by mitochondrial dysfunction with the aim to improve patient outcomes through a precision psychiatry approach. Currently this program is in preclinical phase with an initial focus on mitochondrial energetics. Targeting this metabolic pathway may provide a new treatment approach for subsets of TRD cases.
- **TryptageniX** is a majority-owned joint venture with CB Therapeutics that will specialize in both the discovery of new chemical entities NCEs for the atai pipeline through bioprospecting and on biosynthesis of atai's naturally derived development candidates. Bioprospecting refers to the search for natural products from which medicines can be developed, while biosynthesis is the production of complex molecules within living organisms or cells. Both are central to TryptageniX's approach to the development of NCEs. In addition, the development of innovative biosynthetic methods will further optimize the scalability of compound manufacturing, allowing us to address the escalating mental health crisis in an ecologically sustainable manner.
- **Invyxis** is a wholly owned platform company committed to developing NCEs and to further pioneering next-generation mental health treatments, which will bring proven medicinal chemistry tools and comprehensive biological screening approaches to our growing enterprise of drug discovery and design. Invyxis has entered into a strategic collaboration with Dalriada Drug Discovery, specialists in the discovery of small molecule therapeutics. Invyxis will harness a broad array of methods including structure-based design, synthetic chemistry, high-throughput screening, and in vivo characterization with the goal of discovering new agents with potential in treating mental health disorders, generating NCEs to progress into our research & development pipeline of psychedelic and non-psychedelic compounds. The platform company will initially focus on agonists at the 5-HT2A receptor, recognizing the importance of this key serotonin receptor system in treating a range of mental health disorders.

Our Ownership Position in COMPASS

In addition to our emerging clinical and preclinical programs and enabling technologies, we led the Series A financing round in 2018 for COMPASS, co-led their Series B financing round in 2020 and continue to hold a significant equity ownership position in COMPASS. 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 TRD. The therapeutic potential of psilocybin administered in conjunction with psychological support has been shown in multiple academic-sponsored studies, which did not involve COMP360, specifically exhibiting rapid reductions in depression symptoms after a single high dose with no SAEs. COMPASS evaluated COMP360 in conjunction with psychological support in a Phase 2b trial that concluded in July 2021 and reported its positive Phase 2b data for its proprietary psilocybin COMP360 for TRD in November 2021. The 233-patient trial met its primary endpoint, showing a 6.6-point reduction on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to 3 weeks when comparing the 25mg dose to the 1mg dose. COMP360 also showed both rapid response and durability of efficacy and was generally well tolerated. COMPASS plans to meet with the FDA in April 2022 to discuss the Phase 3 trial design which is anticipated to start in the second half of this 2022.

As of December 31, 2021, we beneficially owned 9,565,774 shares representing 22.8% equity interest in COMPASS. Certain of our founding investors were also seed investors and founders of COMPASS. Our interest in the product candidates of COMPASS is limited to the potential appreciation of our equity interest.

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.

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 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. 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. 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, Praxis Precision Medicines, GH Research, Johnson & Johnson (Janssen Pharmaceuticals), Novartis, NeuroRX and Axsome Therapeutics, as well as COMPASS, in which we hold an equity stake.

Cognitive Impairment Associated with Schizophrenia

We are not aware of any pharmacological treatments approved for CIAS. While antipsychotics are most commonly used to treat psychotic symptoms of schizophrenia, these medications fail to address the cognitive and negative symptoms of schizophrenia and are often associated with severe dose limiting effects. Furthermore over 50 assets in development for CIAS have been discontinued or are inactive, indicating the complexity of successfully developing a therapy for this condition. We are aware of several biopharmaceutical companies with therapies in development for CIAS including Boehringer Ingelheim, Pfizer, Roche, Biogen, Vanda, Sunovion, Neurocrine Biosciences, Novartis and Takeda Pharmaceuticals.

Substance Use Disorder

There are a range of available therapies for different forms of SUD, but we believe that many have limitations. For OUD existing pharmacological treatments are divided into two classes: (i) synthetic opioid receptor agonists, such as buprenorphine and methadone, and (ii) opioid antagonists, such as naltrexone and naloxone. Limitations of these agents include inconvenient treatment regimens, limited access, and an inability to maintain abstinence after medically assisted withdrawal. Currently marketed products include the SUBOXONE,

SUBUTEX and SUBLOCADE brands, marketed by Indivior, VIVITROL, marketed by Alkermes, and BUNAVAIL buccal film, marketed by BioDelivery Sciences, among others.

We are aware of several biopharmaceutical companies with therapies in development for OUD including BioXcel, Opiant and Intra-Cellular Therapies.

Anxiety

Anxiety disorders are generally treated with medication, psychotherapy or both. Treatment often involves use of antidepressants including SSRIs, such as paroxetine, sertraline and citalopram. However, SSRIs typically have a slow onset of action and have 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 and Arvelle Therapeutics.

mTBI

We are not aware of any pharmacological treatments approved for mTBI and there are limited assets in development specifically for the treatment of mTBI. We are aware of several biopharmaceutical companies with therapies in development for forms of traumatic brain injury including SanBio, Vasopharm, Levolta Pharmaceuticals, Oxeia Biopharmaceuticals, Avanir (now Otsuka) and Athersys.

PTSD

There are currently two SSRIs, Zoloft and Paxil, approved for the treatment of PTSD, and these two drugs are generic. There are several other generic products on the market and many drugs currently under development for anxiety and trauma-related disorders are also being evaluated for PTSD, which we believe reflects the limitations of the available therapies and an urgent need for better treatment.
We are aware of several biopharmaceutical companies with therapies in development for PTSD, including MAPS Public Benefit Corporation, Otsuka, Bionomics, Corcept Therapeutics, Aptinyx, Azevan Pharmaceuticals, Bionorica, Seelos Therapeutics and Tonix Pharmaceuticals.

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 December 31, 2021, our intellectual property portfolio includes 17 issued U.S. patents, 154 issued non-U.S. patents, 9 pending U.S. applications; 40 pending non-U.S. applications; and 24 pending provisional applications in the U.S. Our intellectual property portfolio for each of the programs in our pipeline are further described and summarized in the table below. 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	✓		✓	
Neuronasal	NN-101			✓	✓
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

Patents

Perception Neuroscience (PCN-101)
As of December 31, 2021, Perception Neuroscience in-licenses three issued U.S. patents, three foreign issued patents in Japan and 1 foreign issued patent in Europe, four U.S. pending patent applications and 13 foreign pending patent applications in Canada, China, Europe, Hong Kong, Japan and Taiwan 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. As of December 31, 2021, Perception Neuroscience also in-licenses one U.S. pending patent application and eight foreign pending patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel and Japan covering the composition of matter of S-Norketamine for the treatment of depressive symptoms. As of December 31, 2021, Perception Neuroscience also owns 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 one pending U.S. provisional application directed to R-Ketamine salts and pharmaceutical compositions. Perception Neuroscience's owned and in-licensed issued patents and any patents issuing from the owned or in-licensed pending patent applications or patent applications claiming the benefit of the in-licensed PCT patent application, if granted, are expected to expire between 2034 and 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Recognify (RL-007)
As of December 31, 2021, Recognify in-licenses ten issued U.S. patents and 28 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)
As of December 31, 2021, DemeRx IB owns two issued U.S. patents and two foreign issued patents in Europe and Australia, two U.S. pending patent applications, and three foreign pending patent applications in Australia, Europe and Canada covering methods of treatment using ibogaine (DMX-1002). DemeRx IB's issued patent 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. As of December 31, 2021, Atai Life Sciences AG owns one U.S. provisional 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)
As of December 31, 2021, GABA Therapeutics owns two issued U.S. patents, one U.S. pending patent application, four issued foreign patents in Australia, Mexico, Israel and Japan and nine foreign pending patent applications in Australia, Brazil, Canada, China, Republic of Korea, Europe, India and Japan, covering the pharmaceutical composition and corresponding methods of use of the deuterated analogs of etifoxine (GRX-917). GABA Therapeutics' issued patents and any patents issuing from the pending patent applications, if granted, are expected to expire in 2036, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

EmpathBio (EMP-01)
As of December 31, 2021, Atai Life Sciences AG owns two U.S. provisional patent applications, covering prodrugs of MDMA and related compounds and uses thereof. 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. As of December 31, 2021, Atai Life Sciences AG owns three 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 in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Revixia (RLS-01)
As of December 31, 2021, Atai Life Sciences AG owns one U.S. provisional patent application, covering buccal and intranasal compositions of salvinorin A (RLS-01) exhibiting unique PK profiles following administration. Any patents issuing from this pending patent application, if granted, are expected to expire in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Viridia Life Sciences (VLS-01)
As of December 31, 2021, Atai Life Sciences AG owns two U.S. provisional 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. As of December 31, 2021, Atai Life Sciences AG owns five 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 in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

PsyProtix
As of December 31, 2021, Atai Life Sciences AG owns one U.S. provisional patent application, covering products of acylcarnitines. Any patents issuing from this pending patent application, if granted, are expected to expire in 2042, exclusive of possible patent term adjustments or extensions or other forms of exclusivity.

Entheogenix
As of December 31, 2021, Atai Life Sciences AG owns two U.S. provisional patent applications, covering serotonin receptor drugs and pharmaceutical compositions thereof. 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.

Psyber
As of December 31, 2021, Atai Life Sciences AG owns three U.S. provisional patent applications, covering a method using data to determine therapy exercises and contents. 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.

Introspect
As of December 31, 2021, Atai Life Sciences AG owns three U.S. provisional patent applications, covering digital therapeutics to assessing physical and mental health. 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.

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, or 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 preclinical 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 preclinical 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 general investigational plan and the protocol(s) for clinical studies. Some preclinical 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 authorization 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.

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.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

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 agreement 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.

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.

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, preclinical and other 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 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.
The FDA may refer an application for a novel drug to an advisory committee. 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. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it 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 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 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 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 products that meet certain criteria. For example, new 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 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 of 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.

Any product submitted to the FDA for approval, including a product 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. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease 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 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 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 may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and 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, 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 license 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 also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

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 of handlers 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. 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 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 will be 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 non-clinical 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 studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical 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 countries, 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, 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, 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 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 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. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023, and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials 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.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. 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 10 years have elapsed from the initial authorization of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 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 drug designation

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.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication which means that the EU regulatory 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. The application for orphan drug designation must be submitted before the application for MA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may, however, 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 drug destination, for example, where the prevalence of the condition has increased above the threshold or it is judged 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 EU member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. 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 marketing authorization, 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 of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through March 31, 2022, and reduced payments to several types of Medicare providers. 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. 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.

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 mental health care company, 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, 2021, atai had 81 full-time employees and 18 contractors or consultants doing regular work for the company. Our subsidiary companies had six additional full-time employees. Of our full-time employees, 42 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.

Our employee headcount was 29 as of December 31, 2020, and grew by 280% during 2021. 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 2021, in collaboration with all employees, we defined four core atai values: 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. See also the section titled "COVID-19 Business Update" herein.

Recruiting

In 2021, we established 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 endeavor to fill every role with the most qualified candidate possible, which sometimes requires partnership with an external recruitment agency. We are consistently looking at new opportunities and avenues to recruit talented individuals.

The talent acquisition team's focus in 2022 is to meet the growth needs across our companies and subsidiaries. We recognize that our current and potential future team members have many options of where to work, including with other biotech and pharma companies, research and academic institutions, government entities, and consulting and investment firms. To attract and retain 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
In 2021, we established 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 situated on a 9-block grid, which informs promotions, salary adjustments, and annual equity grants.

Core Values and Ethics
In 2021, we defined the four core atai values. 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 75th percentile or above. We link a portion of every employee's compensation to performance through a performance bonus program. To create a sense of ownership and align employee incentives with our long-term success, we offer eligible employees equity ownership in the company through our employee stock purchase plan. 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 (for more relating to our non-profit efforts, please see the section titled "atai Impact" below). 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 a starting point of our Diversity, Equity and Inclusion, or DE&I, 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 2022.

Hybrid office culture
As of December 31, 2021, we had offices in New York, London, and Berlin. In 2022, we opened new offices in Boston and San Diego and will move to a larger office in Berlin. 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.

The key pillars of atai Impact's activities are: advancing education, expanding access, and supporting the wider ecosystem of mental health care. atai Impact has an initial focus on the psychedelics sector, given its emerging potential in tackling the growing mental health crisis. The establishment of atai Impact is based on atai's position that harmonization across commercial and non-profit entities represents the best path forward to address all aspects of the escalating global mental crisis.

In December 2021, atai Impact announced its first major initiative, 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.

In February 2022, atai Impact announced its $500,000 donation to the Multidisciplinary Association for Psychedelic Studies ("MAPS"). The donation is for multi-year support of MAPS' ongoing initiatives, including its Health Equity Program. The program aims to optimize access and healing through the development of a diverse network of therapy providers reflecting the diverse experiences of those who experience trauma and mental health conditions.

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 Krausenstraße 9-10, 10117 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, 2020 and December 31, 2021 was $169.8 million and $167.8 million, respectively. We have no products that are approved for commercial sale and have not generated any 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 as of December 31, 2021, 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 Nasdaq.

We cannot be certain that additional funding will be available on acceptable terms, or at all. For example, market volatility resulting from 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 $24.9 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 $15.0 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 we agreed to make aggregate payments to Recognify Life Sciences of up to $18.0 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 $5.0 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 $0.9 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 $3.9 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, 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 $2.3 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 $2.0 million.

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.

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, it must complete extensive preclinical testing and studies that support the planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the proposed clinical programs or if the outcome of preclinical studies will ultimately support the further development of the programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical 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, the EMA 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 protocols 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, the EMA 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. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023, and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

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 new drug candidates designed to target major depressive disorder, or MDD, failed to meet their primary endpoints in Phase 3 clinical trials. The NDA for ALKS 5461, another new 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.

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, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). 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 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. If original marketing approval of a drug was obtained via an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. 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.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our, our ability to commercialize and generate revenue. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.
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.

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 recently 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 are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). While the legislation and proposed regulations include the CCPA and CPRA contain an exception for activities that are subject to HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business. 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 the event we decide to conduct additional clinical trials or continue to enroll subjects in our ongoing or future clinical trials in the EU, we may be subject to additional privacy restrictions. The collection and use of personal data, including health-related data, in the EU is governed by the provisions of the General Data Protection Regulation 2016/679, or GDPR. The GDPR went into effect in May 2018 and imposes strict requirements for processing personal data. 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, and taking certain measures when engaging third-party processors. 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 total worldwide annual turnover of the preceding financial year, whichever is higher. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; 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 and imposing further restrictions on use of the standard contractual clauses, or SCCs, which could increase our costs and our ability to efficiently process personal data from the EEA. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the United Kingdom SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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.
Additionally, from January 1, 2021, companies have had to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. 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 UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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. On December 27, 2018, the District Court for the District of Columbia invalidated that formula change, ruling the change was not an "adjustment" that was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation, and such a dramatic change was beyond the scope of the Secretary's authority. On July 31, 2020, the U.S. Court of Appeals for the District of Columbia reversed the District Court's decision. Based on the D.C. Circuit's decision, CMS proposed for calendar year 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on, for a net payment rate of ASP minus 28.7, or continue to pay ASP minus 22.5 percent. In December 2020, CMS instead finalized its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs, effective January 1, 2021. 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 of 2 percent per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring

more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The likelihood of implementation of any of these reform initiatives is uncertain and could materially impact the regulation governing our product candidates, if approved.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

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 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. Though 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, it 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, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, 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.

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, Lars Christian Wilde, our co-founder, 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 continue expanding our organization and may experience difficulties in managing this growth, which could disrupt our operations.

As we mature, we expect to continue to expand our full-time employee base and to 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 the 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. If our management is unable to effectively manage our 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), 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. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. 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, 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.

Cyber-attacks 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 cyber-attacks or successfully mitigating their effects. The risk of a security breach or disruption, particularly through cyber-attacks 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. 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 cyber-attacks of our IT networks, such as through phishing scams and ransomware. Although none of these actual or attempted cyber-attacks has had a material adverse impact on our operations or financial condition, we cannot guarantee that such incidents will not have such an impact in the future.

Any cyber-attack 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, as well as factors related to and as a result of the COVID-19 pandemic. 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, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, 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. Regulatory authorities outside the United States have adopted 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 may ultimately impact our business and operations, including our research and development programs and related clinical trials, will largely depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the pandemic, the spread of the disease and variants thereof, the effectiveness of vaccines and continued 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.
In response to the ongoing COVID-19 pandemic, we have taken 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, such as the duration or severity of the pandemic or the effectiveness of containment actions or treatments.

While we are working 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, we expect there could be 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 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. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. We cannot currently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience repeated shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition and results of operations.

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.

We expect to be classified as a passive foreign investment company, 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. Based on our historic and anticipated operations and composition of assets, we may be a PFIC for the current taxable year and for the foreseeable future. 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. 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, or 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, 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 each CFC in our group (if any), which may subject such person to adverse U.S. federal income tax consequences. Specifically, a United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of such CFC's "Subpart F income," "global intangible low-taxed income" and investments in U.S. property, whether or not we make any distributions of profits or income of such CFC to such United States shareholder.

If you are treated as a United States shareholder of a CFC, 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.

We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.

The relevant national law, case law and Organization for Economic Cooperation and Development ("OECD") guidelines suggest that a company is likely to be regarded as a German tax resident if (i) most meetings of its management board are held in Germany with a majority of directors present in Germany for those meetings which are properly minuted; (ii) at those meetings there are full discussions of, and decisions are made regarding the key strategic issues affecting the company and its subsidiaries; (iii) the important day to day business decisions outside of board meetings are made in Germany; (iv) some of the directors of the company, together with supporting staff, are based in Germany; and (v) the company has permanent staffed office premises in Germany.

In addition, the OECD, with the support of the Group of Twenty ("G20"), initiated the base erosion and profit shifting ("BEPS") project in 2013 in response to concerns that changes were needed to international tax laws. In November 2015, the G20 finance ministers adopted final BEPS reports designed to prevent, among other things, the artificial shifting of income to low-tax jurisdictions, and legislation to adopt and implement the standards set forth in such reports has been enacted or is currently under consideration in a number of jurisdictions. In May 2019, the OECD published a "Programme of Work," which was divided into two pillars. 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. More recently, on October 10, 2021, 136 member jurisdictions of the G20/OECD Inclusive Framework on BEPS joined the "Statement on a Two-Pillar Solution to Address the Tax Challenges Arising from the Digitalisation of the Economy" which sets forth the key terms of such two-pillar solution, including a reallocation of taxing rights among market jurisdictions under Pillar One and a global minimum tax rate of 15% under Pillar Two. 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 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 that are not considered (deemed) Dutch tax residents or perform activities in the Netherlands that constitute a permanent establishment.

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 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. For more information, see "—We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us." 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 will be limited.

We have net operating losses, or NOLs, in various jurisdictions including Germany and the United States. Our ability to utilize our NOLs in Germany is currently limited and may be limited further, under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz – KStG*) and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz – GewStG*). As of December 31, 2021, our German NOL carryforward was approximately $102.7 million. These limitations 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, 2021, we had U.S. federal NOLs of $39.7 million. In addition, under Section 382 of the United States Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a cumulative change, by value, in our ownership by "5-percent 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.

In the future we may be subject to tax proceedings. Any changes in tax proceedings could have a material adverse effect on our business, financial condition and results of operations.

We calculate and provide for income taxes in each tax jurisdiction in which we operate on the basis of local interpretation of legislations and general accepted accounting policies which often involves complex matters and judgment. Our judgments may not be sustained as a result of disagreement by the tax authorities with our judgments and the amounts ultimately paid could be different from the amounts

previously recorded. In addition, changes in tax laws, treaties or regulations, or their interpretation or enforcement, may be unpredictable and could become more stringent, which could materially adversely affect our tax position. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our International Operations

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

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

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- our failure to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, including the ongoing military conflict between Russia and Ukraine, 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 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 European Union and the European Economic Area on January 31, 2020, also known as Brexit, and entered into a transition period that ran until December 31, 2020, during which the United Kingdom continued its ongoing and complex negotiations with the European Union relating to the future trading relationship between the parties.

On December 24, 2020, the United Kingdom and the European Union announced that they had struck a new bilateral trade and cooperation agreement governing the future relationship between the United Kingdom and the European Union, or the EU-UK Trade and Cooperation Agreement. The EU-UK Trade and Cooperation Agreement was formally approved and signed by the parties on December 30, 2020 and took full effect on May 1, 2021.

The EU-UK Trade and Cooperation Agreement provides clarity in respect of the intended shape of the future relationship between Great Britain and the European Union and detailed matters of trade in goods and cooperation. Specific rules apply to the relationship between the European Union and Northern Ireland which while being a constituent part of the United Kingdom has a different relationship with that of the European Union than the relationship introduced by the EU-UK Trade and Cooperation Agreement in respect of Great Britain and the European Union. There is no certainty as to the evolution of such special rules as they apply to Northern Ireland's relationship with that of the rest of Great Britain nor with Northern Ireland's relationship with the European Union.

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.

There remain unavoidable uncertainties related to the EU-UK Trade and Cooperation Agreement and the new relationship between the United Kingdom and the European Union, which will continue to be developed and defined including in relation to trade in goods. Significant political and economic uncertainty remains about whether the terms of the relationship under the EU-UK Trade and Cooperation Agreement will differ materially from the terms before Brexit. There can be no assurance that the uncertainty regarding Brexit will not have an adverse effect on our business.

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.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth 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 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 cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. 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 no longer a "smaller reporting company" and, as a result we are subject to certain enhanced disclosure requirements.

As of December 31, 2021, we are no longer a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. Since we are no longer a smaller reporting company, beginning with our quarterly report on Form 10-Q for the quarter ending March 31, 2022, we will be unable to provide simplified executive compensation disclosure or take advantage of certain other reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We expect that the loss of smaller reporting company status and compliance with the related additional disclosure requirements will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements.

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, 2021, Apeiron held an 18.0% 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.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate the material weaknesses, or if other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports as a public company in a timely manner.

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2021, we identified material weaknesses in our internal control over financial reporting. 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 our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that were 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. These deficiencies constitute material weaknesses in the design of our internal controls over financial reporting. As a result of the material weaknesses, we have relied, in part, on the assistance of outside advisors with expertise in these matters to assist us in the preparation of our consolidated financial statements and in our compliance with SEC reporting obligations while we remediate these material weaknesses.

We are implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel and engaging financial consultants to enable the implementation of internal control over financial reporting and segregating duties amongst accounting and finance personnel; and planning to implement certain accounting systems to automate manual processes. We will also continue to engage third parties as required to assist with technical accounting, application of new accounting standards, tax matters, valuations of our equity instruments, contingent consideration, notes receivable and acquired in-process research and development.

While we are working to remediate the material weaknesses, we cannot at this time, provide an estimate of the timeframe we expect in connection with implementing our plan to remediate the material weaknesses. These remediation measures may be time consuming, costly, and might place significant demands on our financial and operational resources. If we are unable to successfully remediate our existing material weaknesses, or other material weaknesses that may occur in the future, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remediate any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act and are therefore required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. As a public company, management is required to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment includes the disclosure of any material weaknesses in our internal control over financial reporting identified by management. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected

material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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.

Prior to becoming public, our business had historically operated as a privately owned company. As a public company we have, and expect to continue to, incur significant legal, accounting, reporting and other expenses as a result of having publicly traded common shares. 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.

As a public company, and particularly after we no longer qualify as an emerging growth company, we will continue to incur significant legal, accounting and other expenses related to our operation as a public company. The Sarbanes-Oxley Act of 2002 (SOX), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, or 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 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.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of SOX, which will require management to certify financial and other information in our annual reports and, beginning with our second annual report, to provide an annual management

report on the effectiveness of control over financial reporting. Though we are required to disclose material changes in internal control over financial reporting, we will not be required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 of SOX (Section 404) until our second annual report. While we remain an emerging growth company, we will not 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 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. 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. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Item 1B. Unresolved Staff Comments.
None.

Item 2. Properties.
Our principal executive office is located at Krausenstraße 9-10, 10117 Berlin, Germany, where we lease approximately 430 square feet of office space at pursuant to a lease based on a two-month rolling contract. We also lease office space in other locations including London, the United Kingdom; New York, New York; and Boston, Massachusetts. 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, 2022, there were 149 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 Reports on Form 10-Q for the quarters ended June 30, 2021 and September 30, 2021 filed with the SEC on August 16, 2021 and November 15, 2021, respectively, there were no sales of unregistered equity securities during the year ended December 31, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Use of Proceeds

On June 22, 2021, we completed our initial public offering and issued and sold 17,250,000 of our common shares (including 2,250,000 common shares in connection with the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $15.00 per share.

As of December 31, 2021, net proceeds of approximately $231.6 million from our initial public offering have been invested in a variety of capital preservation investments, including term deposits, and short-term, investment-grade and interest-bearing instruments. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus dated June 17, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act, relating to our Registration Statements on Form S-1 (File No. 333-255383).

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 as a 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, including psychedelic compounds and digital therapeutics. We have built a pipeline of 13 drug and discovery programs and four enabling technologies, each led by focused teams with deep expertise in their respective fields and supported by our internal development and operational infrastructure. We believe that several of our therapeutic programs' target indications have potential market opportunities of at least $1 billion in annual sales, if approved. One of our atai companies, Recognify Life Sciences, has completed a Phase 2a proof-of-mechanism trial in the United States. In addition, we initiated Perception's Phase 2a proof-of-concept trial for TRD, and DemeRx's Phase 1/2a OUD trial in the third quarter of 2021.

Our business is organized along three strategic pillars:

- **Rapid acting intervention**: first, second, and third generation compounds that result in rapid-acting improvement of mental health disorders;
- **Ongoing digital support**: additional care that is provided to patients before, during, and after initial treatment interventions; and
- **Biomarker-driven precision mental health**: the identification of patient sub-types using biological and digital biomarkers.

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 development of our programs and enabling technologies 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 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. 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. Examples of specific services we provide include project management, research and development, market strategy and development and corporate finance.

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 2,500,000 shares 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 $167.8 million and $169.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and December 31, 2020, our accumulated deficit was $357.8 million and $190.0 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 and 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 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 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, 2021, we had cash and cash equivalents of $362.3 million. We believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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 and from issuances of convertible notes.

Our Emerging Clinical and Preclinical Programs

The table below summarizes the status of our product candidate portfolio as of the filing date of this Annual Report. Our pipeline currently consists of therapeutic candidates across multiple neuropsychiatric indications including depression, cognitive impairment associated with schizophrenia, or CIAS, OUD, anxiety, mTBI and PTSD. We rely on third parties to conduct our preclinical and clinical trials and, as such, progress and timing of these preclinical and clinical trials and related milestone events, including those discussed in greater detail below, may be impacted by several factors including, but not limited to, changes in existing or future contractual obligations or arrangements with these third parties, geographic developments, such as site locations or regulatory requirements, and other changing circumstances associated with these third parties and the clinical trial sites. See the section titled "Risk Factors —Risks Related to Reliance on Third Parties" in this Form 10-K. We currently hold at least a majority interest, or have options to obtain a majority interest, in each of these atai companies.

Program	Lead Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Affiliate Company[1]
PCN-101 / R-ketamine	Treatment-Resistant Depression						Perception Neuroscience
RL-007 / Compound[2]	Cognitive Impairment Associated With Schizophrenia						Recognify Life Sciences
GRX-917 / Deuterated etifoxine	Generalized Anxiety Disorder						GABA Therapeutics
DMX-1002 / Ibogaine	Opioid Use Disorder						DemeRx IB
KUR-101 / Deuterated mitragynine	Opioid Use Disorder						Kures
RLS-01 / Salvinorin A	Treatment-Resistant Depression						Revixia Life Sciences
VLS-01 / DMT	Treatment-Resistant Depression						Viridia Life Sciences
EMP-01 / MDMA derivative	Post-Traumatic Stress Disorder						EmpathBio
NN-101 / N-acetylcysteine	Mild Traumatic Brain Injury						Neuronasal
Undisclosed	Treatment-Resistant Depression						PsyProtix
Discovery engines	Multiple lead indications						Multiple affiliate companies[3]
LIMITED TO EQUITY INTEREST							
Developing COMP360, a formulation of psilocybin, administered with psychological support from specially trained therapists, for treatment-resistant depression. Phase 2b topline data read out in Nov '21.							Compass Pathways
Developing DMX-1001, a formulation of noribogaine, as a potential at-home maintenance therapy for OUD. Preclinical stage.							DemeRx NB

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

(1) Perception, Recognify, DemeRx IB, Kures, and Neuronasal are all variable interest entities; GABA is a non-consolidated VIE with operational involvement through MSA model, including Srinivas Rao serving as CMO; EmpathBio, Revixia and Viridia are wholly-owned subsidiaries; COMPASS Pathways and DemeRx NB are non-controlling equity interests.

(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) Including EntheogeniX, TryptageniX, Invyxis

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

Perception Neuroscience: PCN-101 for TRD

- **Product concept**: PCN-101 is a parenteral formulation of R-ketamine, a glutamatergic modulator that is a component of racemic ketamine and is being developed as a rapid-acting antidepressant, with the potential to be an at-home non-dissociative alternative to S-ketamine (marketed as SPRAVATO).
- **Prior evidence in humans**: In a third-party clinical trial, another formulation of R-ketamine was observed to produce a rapid and durable response with limited dissociative side effects in patients with TRD. In September 2020, Perception Neuroscience completed a Phase 1 trial of PCN-101 supporting the advancement of PCN-101 into a Phase 2a proof-of-concept trial. In September 2021, the Phase 2a proof-of-concept trial of PCN-101 for TRD was initiated.
- **Upcoming milestones**: In December 2021, the FDA gave Investigational New Drug ("IND") clearance for the development of PCN-101 for the treatment of TRD. In September 2021, the Phase 2a proof-of-concept trial of PCN-101 for TRD was initiated. This randomized, double-blind, placebo-controlled Phase 2a proof-of-concept trial is designed to assess the efficacy, safety, dose response, and duration of response in patients with TRD. A topline data readout of this trial is expected by the end of 2022. We also anticipate results from a PCN-101 Phase 1 trial that bridges between the current intravenous formulation to a subcutaneous formulation to support at-home use, by the end of 2022.

Recognify Life Sciences: RL-007 for CIAS

- **Product concept**: RL-007, a cholinergic, glutamatergic and GABA-B receptor modulator, is an orally available compound that is thought to alter the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. We are developing this compound for the treatment of CIAS.
- **Prior evidence in humans**: In third-party studies, other formulations of this compound have been shown to effect a significant improvement in aspects of cognitive function in both experimental paradigms involving healthy subjects as well as in a Phase 2 trial in patients suffering from diabetic peripheral neuropathic pain. In April 2021, Recognify initiated a Phase 2 proof-of-mechanism study for RL-007 in 32 CIAS patients, after receiving IND clearance from the U.S. Food and Drug Administration to commence clinical trials for the treatment of CIAS. The study was designed to evaluate the effects of RL-007 on safety, tolerability, electroencephalogram-based biomarkers and cognition.
- **Recent advancements**: In December 2021, we announced positive biomarker data from the Phase 2a proof-of-mechanism study of RL-007 in CIAS patients. RL-007 was well tolerated and demonstrated a clinically meaningful behavioral pro-cognitive profile consistent with previous Phase 1 and 2 trials of this compound. Changes in quantitative electroencephalogram ("qEEG") consistent with a previous Phase 1 trial involving a scopolamine challenge were noted. These results support the progression of RL-007 to a double-blind, placebo-controlled Phase 2a proof-of-concept trial with the goal of demonstrating the pro-cognitive benefit of RL-007 in CIAS.
- **Upcoming milestones**: We anticipate the Phase 2a proof-of-concept trial to be initiated in the second half of 2022.

GABA: GRX-917 for GAD

- **Product concept**: GRX-917 is an oral formulation of a deuterated version of etifoxine, a compound that has a long history of prescription use in France and other countries for treating anxiety disorders. GRX-917 is designed to provide rapid anxiolytic activity with improved tolerability compared to current treatments for anxiety available in the United States.
- **Prior evidence in humans**: Etifoxine has been observed to have the rapid onset of anxiolytic activity of benzodiazepines without their sedating or addicting properties. Furthermore, etifoxine is not associated with abuse, dependence or respiratory depression and has been observed to have no significant impact on motor skills or cognition.
- **Recent advancements**: In June 2021, GABA initiated a Phase 1 single and multiple ascending dose trial of GRX-917. The ongoing Phase 1 trial is a randomized, double-blind, placebo-controlled study of the safety, tolerability and pharmacokinetics of single-ascending and multiple-ascending doses of GRX-917 administered orally to healthy volunteers.
- **Upcoming milestones**: Topline data for this trial is expected by mid-year 2022 and the initiation of a Phase 2a proof-of-concept trial is anticipated to follow in the second half of this year.

DemeRx IB: DMX-1002 for OUD3

- **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, that we are developing for the treatment of OUD.
- **Prior evidence in humans**: In third-party studies evaluating other formulations of ibogaine, significant reductions in opioid cravings were observed, both at discharge and at one month post treatment, and were associated with improved mood in patients with OUD.
- **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 opioid use disorder.
- **Upcoming milestones**: We expect safety data from the phase 1 element of the trial in the second half of 2022.

Kures: KUR-101 for OUD

- **Product concept**: KUR-101 is an oral formulation of deuterated mitragynine being developed for the treatment of OUD. Mitragynine is a component of the leaves of kratom (Mitragnyna speciosaz).
- **Prior evidence in humans**: 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**: KUR-101 is a Phase 1 randomized, double-blind, two-part study of the safety, tolerability, pharmacokinetics, analgesic and respiratory effects of KUR-101 in healthy volunteers. Part 1 is a 5 cohort ascending dose design of a single dose of KUR-101. Part 2 is a three-period crossover design to compare the analgesic and respiratory effects of a single oral dose of KUR-101, a single oral dose of OxyNorm®, and a single oral dose of placebo in healthy male volunteers.
- **Upcoming milestones**: A Phase 1 single ascending dose trial to evaluate the maximum tolerable dosage was initiated, with first patient dosed in March and topline results expected in the second half of 2022.

Revixia Life Sciences: RLS-01 for TRD

- **Product concept**: RLS-01 is a formulation of SalA, a naturally occurring dissociative hallucinogenic compound, with pharmacology differentiated from that of psilocybin or DMT, being developed for the treatment of TRD and other indications.
- **Prior evidence in humans**: In a third-party study of another formulation of SalA, the effects of the compound were observed to be similar to those of psilocybin based upon functional brain imaging. We believe these data combined with anecdotal usage reports suggest that SalA may possess rapid-acting antidepressant properties.
- **Upcoming milestones**: RLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the second half of 2022.

Viridia Life Sciences: VLS-01 for TRD

- **Product concept**: VLS-01 is a formulation of DMT, the active moiety of the traditional, hallucinogenic drink ayahuasca. DMT is characterized by an intrinsically short duration of psychedelic effect with a serum half-life estimated at less than 10 minutes. VLS-01 is formulated to provide a psychedelic experience lasting 30 to 45 minutes, thus potentially allowing for a shorter clinic visit compared to many other psychedelic compounds that may require a patient to be monitored for four or more hours.
- **Prior evidence in humans**: Ayahuasca administration was shown to provide significant antidepressant effects compared with placebo at one, two and seven days after dosing in a double-blind, randomized, placebo-controlled third-party clinical trial in patients with TRD.
- **Upcoming milestones**: VLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the middle of 2022. The study will utilize buccal and IV formulations in healthy adult volunteers to assess the relative bioavailability of the buccal versus IV formulations, the safety and tolerability of VLS-01 administered by both routes, as well as pharmacodynamics using qEEG and other measures.

EmpathBio: EMP-01 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 for the potential to have an improved therapeutic index compared to racemic MDMA.
- **Prior evidence in humans**: 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 with 90 patients with severe PTSD, showed statistically significant reduction in PTSD symptoms in the MDMA-assisted psychotherapy group versus placebo.
- **Upcoming milestones**: EMP-01 is in preclinical development for PTSD with a Phase 1 trial expected to be initiated in the second half of 2022.

Neuronasal: NN-101 for mTBI

- **Product concept**: NN-101 is a novel intranasal formulation of NAC. NAC is believed to stimulate the synthesis of GSH, an endogenous antioxidant that plays a protective role in the pathogenesis of mTBI.
- **Prior evidence in humans**: An orally administered formulation of NAC was shown to increase the probability of mTBI symptom resolution at seven days in a third-party study conducted by the U.S. Army. Neuronasal has also completed a pilot study of NN-101 in nine healthy volunteers. In this pilot study, NN-101 was observed to be approximately 20 times and 100 times more brain-penetrant compared to IV and oral NAC, respectively, and was well tolerated.

Our Ownership Position in COMPASS

In addition to our emerging clinical and preclinical programs and enabling technologies, we led the Series A financing round in 2018 for COMPASS, co-led their Series B financing round in 2020 and continue to hold a significant equity ownership position in COMPASS. 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 TRD. The therapeutic potential of psilocybin administered in conjunction with psychological support has been shown in multiple academic-sponsored studies, which did not involve COMP360, specifically exhibiting rapid reductions in depression symptoms after a single high dose with no SAEs. COMPASS evaluated COMP360 in conjunction with psychological support in a Phase 2b trial that concluded in July 2021 and reported its topline data in November 2021. The Phase 2b trial produced positive results that showed patient improvements beyond reduction of depression symptoms, including in positive affect and quality of life. The randomized, double-blind, dose-ranging study investigated the safety and efficacy of psilocybin therapy in 233 patients, the largest clinical trial with psilocybin to date. COMPASS also launched a Phase 2 study of COMP360 psilocybin therapy for post-traumatic stress disorder. As of December 31, 2021, we beneficially owned 9,565,774 shares representing a 22.8% equity interest in COMPASS. Certain of our founding investors were also seed investors and founders of COMPASS. Our interest in the product candidates of COMPASS is limited to the potential appreciation of our equity interest.

Our Enabling Technologies

We believe our enabling technologies have the potential to support the development of our pipeline and be used as patient support tools. We currently have four enabling technologies housed at our atai companies: Introspect Digital Therapeutics, InnarisBio and Psyber, as well as IntelGenx Technologies, a strategic investment of ours. None of our existing programs were developed using these enabling technologies, and many of these technologies remain in early stage testing and development. We intend to use these enabling technologies to support the future development of our programs. For more information regarding our enabling technologies, see the section titled “Enabling Technologies” in Part 1, Item 1 of this Form 10-K.

Our Drug Discovery Companies

We also believe in the development of innovative and scalable solutions to better meet patient needs. In November 2019, we acquired a majority interest in EntheogeniX Biosciences, a controlled variable interest entity, that is an AI-enabled computational biophysics platform designed to optimize and accelerate drug discovery. PsyProtix, a majority owned subsidiary we launched in February 2021, is developing metabolomics-based biomarkers that stratify TRD patients with the aim to improve patient outcomes through a precision psychiatry approach. In addition, in December 2021 and January 2022, respectively, we announced the launch of two new companies to support this commitment in driving next-generation approaches in the treatment of mental health disorders, TryptageniX and Invyxis. These two companies’ approaches to drug discovery are highly complementary to that of EntheogeniX, our existing AI-enable drug discovery company, of which we acquired a majority interest in 2019. TryptageniX will specialize in both the discovery of new chemical entities (“NCEs”) for our pipeline through bioprospecting and on biosynthesis of our naturally derived development candidates and Invyxis will bring proven medicinal chemistry tools and comprehensive biological screening approaches to our growing enterprise of drug discovery and design. Expanding intellectual property has been essential to our strategy since inception, with key investments made to unlock NCEs. We have already made substantial progress in our drug discovery efforts to date, synthesizing and screening approximately 300 compounds

and identifying novel scaffolds that display potential in targeting mental health disorders. For more information regarding our drug discovery companies, see the section titled “Drug Discovery Companies” in Part 1, Item 1 of this Form 10-K.

Factors Affecting our Results

We believe that the most significant factors affecting our results of operations include:

Research and Development Expenses

Our ability to successfully develop innovative product candidates through our programs will be the primary factor affecting our future growth. Our approach to the discovery and development of our product candidates is still being demonstrated. As such, we do not know whether we will be able to successfully develop any of our product candidates. Developing novel product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. We have chosen to leverage our platform to initially focus on advancing our product candidates in the area of mental health.

All of our product candidates are still in development stages, and we have incurred and will continue to incur significant research and development costs for preclinical studies and clinical trials. We expect that our research and development expenses will constitute the most substantial part of our expenses in future periods in line with the advancement and expansion of the development of our product candidates.

Acquisitions/Investments

To continue to grow our business and to aid in the development of our various product candidates, we are continually acquiring and investing in companies that share our common goal towards advancing transformative treatments, including psychedelic compounds and digital therapeutics, for patients that suffer from mental health disorders. For the year ended December 31, 2021, our net cash outflow was $1.0 million in relation to the acquisition of TryptageniX, Inc., which represents the portion of the total cash consideration that was paid to the seller. The remaining cash was paid to acquire majority equity in TryptageniX, which is a consolidated variable interest entity ("VIE") and is included in our consolidated financial statements. For the year ended December 31, 2021, our net cash outflow was $76.6 million in relation to equity method investments and other investments. For the year ended December 31, 2020, our net cash outflow was $0 in relation to acquiring Recognify, Inc. For the year ended December 31, 2020, our net cash outflow was $26.0 million in relation to equity method investments and other investments.

Acquisition of In-Process Research and Development Expenses

In an asset acquisition, including the initial consolidation of a VIE that is not a business, acquired in-process research and development, or IPR&D, with no alternative future is charged to the consolidated statements of operations as a component of operating expenses at the acquisition date.

Since inception, we have grown primarily by continually acquiring and investing in other companies. Our IPR&D expenses were $15.5 million and $12.0 million, representing 9.9% and 11.5% of our total operating expenses for the years ended December 31, 2021 and 2020, respectively. As we continue to acquire and invest in companies, we expect our IPR&D expenses to increase.

Stock-Based Compensation

In August 2020, we adopted the 2020 Equity Incentive Plan and the Hurdle Share Option Plan, which allowed us to grant stock-based awards to executive officers, directors, employees and consultants. Prior to our IPO, we issued stock options that vest over a two to four-year service period, only if and when a “Liquidity Event” (as defined in the plans) occurs, with accelerated vesting if a Liquidity Event occurred by specified dates. Upon the closing of our IPO, the stock-based award vesting contingent upon a Liquidity Event was no longer deferred. For the years ended December 31, 2021 and 2020, we incurred $63.4 million and $67.2 million of stock-based compensation expense, respectively.

Impact of COVID-19

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, we have not experienced material financial impacts on our 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. We continue to monitor the impact of the COVID-19 pandemic on our employees and business, including working remotely on a part or full time basis, and have, and will continue to, undertake business

continuity measures to mitigate potential disruption to our operations and safety of our employees. 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 of this Form 10-K.

Financial Overview

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 development of our programs and enabling technologies 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 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.

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

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 recorded under 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.

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 and from issuances of convertible notes.

We were incorporated pursuant to the laws of the Netherlands on September 10, 2020. As more fully described in the section titled "Business" and Note 1 to our Consolidated Financial Statements appearing elsewhere in this Form 10-K, we undertook a corporate reorganization ("Corporate Reorganization") on April 23, 2021. In April 2021, all of the outstanding shares in ATAI Life Sciences AG were contributed and transferred to ATAI Life Sciences N.V. in a capital increase in exchange for newly issued common shares of ATAI Life Sciences N.V. on a 1 to 10 basis, and, as a result, ATAI Life Sciences AG became a wholly owned subsidiary of ATAI Life Sciences N.V. Furthermore, on June 7, 2021, shares of ATAI Life Sciences N.V. were split applying a ratio of 1.6 to one. The Corporate Reorganization 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 Life Sciences N.V. for accounting and reporting purposes. All share, per-share and financial information presented and corresponding disclosures 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 N.V. with identical restrictions.

On June 22, 2021, we completed an IPO on Nasdaq, in which we issued and sold 17,250,000 of our common shares at a public offering price of $15.00 per share, including 2,500,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, 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 $167.8 million and $169.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and December 31, 2020, our accumulated deficit was $357.8 million and $190.0 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 VIE 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 and 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 development of our mental health research programs. As a result, we anticipate that 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.

As of December 31, 2021, we had cash and cash equivalents of $362.3 million. We believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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.

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.

The tables below show our principal subsidiaries as of December 31, 2021.

Wholly owned subsidiaries

Consolidated Entities	Date of Formation
ATAI Life Sciences AG	February 2018
ATAI Life Sciences US Inc.	February 2019
ATAI Life Sciences UK Ltd	March 2021
Viridia Life Sciences, Inc.	June 2020
IntroSpect Digital Therapeutics, Inc.	June 2020
EmpathBio, Inc.	June 2020
Revixia Life Sciences, Inc.	October 2020
Invyxis, Inc.	December 2021

Consolidated VIEs

Consolidated Entities	Date Control Obtained	Ownership % December 31, 2021
Perception Neuroscience Holdings, Inc.	November 2018	58.9%
Kures, Inc.	August 2019	54.1%
EntheogeniX Biosciences, Inc.	November 2019	80.0%
DemeRx IB, Inc.	December 2019	59.5%
Recognify Life Sciences, Inc.	November 2020	52.0%
PsyProtix, Inc.	February 2021	75.0%
Psyber, Inc.	February 2021	75.0%
InnarisBio, Inc.	March 2021	82.0%
Neuronasal, Inc.	May 2021	56.5%
TryptageniX Inc.	December 2021	65.0%

Investments Accounted for Under the Equity Method

Investee	Common Stock Ownership Percentage[1] as of December 31, 2021
Innoplexus A.G.[2]	35.0%
COMPASS Pathways plc[3]	22.8%
GABA Therapeutics, Inc[4]	7.5%
Neuronasal, Inc[5]	N/A

(1) Common stock ownership percentage represents our common stock ownership percentage of our equity method investee's outstanding common stock.

(2) In February 2021, we entered into a Share Purchase and Assignment Agreement to sell our shares of common and preferred stock held in Innoplexus to a current investor of Innoplexus. The transaction was accounted for as a secured financing as it did not qualify for sale accounting under ASC Topic 860, *Transfers and Servicing*. Refer to Note 5 to our consolidated financial statements appearing elsewhere in this Annual Report for further information.

(3) On August 7, 2020, as part of a corporate reorganization, all shareholders of COMPASS Pathfinder Holdings Limited exchanged their shares for newly issued shares of COMPASS Rx Limited. COMPASS Rx Limited was re-registered as a public limited company and renamed COMPASS Pathways plc, effective on August 21, 2020.

(4) We are deemed to have significant influence over this entity through our total ownership interest in the entity's equity, including our investment in the respective entity's preferred stock.

(5) Neuronasal common stock was accounted for under the equity method until the entity was consolidated on May 17, 2021.

Investments held at fair value

As permitted under Accounting Standards Codification 825, Financial Instruments, or ASC 825, we have elected the fair value option to account for our investment in common shares of IntelGenx. In accordance with ASC 825, we record this investment at fair value under the Other investments held at fair value in our consolidated balance sheets. We received the IntelGenx common shares, warrants and additional unit warrants in May 2021. The fair value of the investment in IntelGenx as of December 31, 2021 was $0. Refer to Note 5 to our consolidated financial statements appearing elsewhere in this Annual Report for further information.

Other Investments

Investee	Date First Acquired
Juvenescence Limited	June 2018
GABA Therapeutics, Inc.	August 2019
DemeRx NB, Inc.	December 2019
Neuronasal, Inc.[1]	December 2019

(1) Neuronasal common stock was accounted for under the equity method until the entity was consolidated on May 17, 2021.

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. The remaining deferred revenue balance related to the Otsuka Agreement is not material as of December 31, 2021. To date, there have been no milestones achieved under the Otsuka Agreement. License revenue of $20.4 million was recorded for the year ended December 31, 2021.

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, 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.

We do not allocate internal research and development expenses consisting of employee and contractor-related costs, to specific product candidate programs because these costs are deployed across multiple product candidate programs under research and development and, as such, are separately classified.

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 IPR&D expenses consist of acquired in-process research and development with no future alternative use based on the probability of clinical success. We expect our acquisition of IPR&D expenses to increase as we continue to grow and expand.

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, which include allocated expenses for rent and maintenance of facilities, 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 also have incurred increased expenses associated with being a public company, including increased costs for accounting, 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 Short Term Notes Receivable—Related Party

Changes in fair value of short term notes receivable—related party, including interest, consists of subsequent remeasurement of our short term notes receivable-related party with COMPASS for which we have elected the fair value option. The COMPASS notes were converted during 2020. See "—Liquidity and Capital Resources—Indebtedness" below for further discussion of our short term notes receivable – related party.

Change in Fair Value of Convertible Promissory Notes

Changes in fair value of convertible promissory notes consists of subsequent remeasurement of our convertible promissory notes for which we have elected the fair value option. The promissory notes were converted during 2020. See "—Liquidity and Capital Resources—Indebtedness" below for further discussion of our convertible promissory notes.

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 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.

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 the consolidated statements of operations. Subsequently, changes in fair value of the common shares, the warrants and additional unit warrants are recorded as a component of other income (expense), net in the consolidated statement of operations.

Unrealized Gain on Other Investments

In March 2020, we entered into a series of transactions including the purchase of additional shares of COMPASS Series A and Series B preferred stock under the secondary Series A preferred stock purchase agreement and the Series B preferred stock subscription agreement, respectively. In April 2020, COMPASS entered into a Series B preferred stock subscription agreement with other investors for issuance of its Series B preferred stock, which resulted in the automatic conversion of our COMPASS convertible notes receivable into shares of COMPASS Series B preferred stock. We remeasured our investment in COMPASS' Series A preferred shares to fair value due to the observable price change in connection with COMPASS' secondary Series A preferred stock purchase in March 2020 and recognized unrealized gains on other investments in the consolidated statements of operations in association with the transaction.

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.

Loss on Asset Acquisition of a Variable Interest Entity

Loss on asset acquisition of a VIE resulted from the purchase of shares of Recognify in November 2020. We measured the assets acquired, liabilities assumed and noncontrolling interest in the transaction based on their fair values as of the acquisition date, resulting in a loss of $0.5 million in our consolidated statements of operations for the year ended December 31, 2020.

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.

Foreign exchange gain (loss), net

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

Other Income (Expense), net

Other income (expense), net consists principally of interest expense and impairment related to our other investments.

Benefit From (Provision For) Income Taxes

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

We regularly assess the need to record a valuation allowance against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Accordingly, we maintain a full valuation allowance against net deferred tax assets as of December 31, 2021 in certain jurisdictions, consistent with prior periods, which primarily relate to our German and international tax loss carryforwards and temporary timing differences related to share-based compensation. We recognize net deferred tax assets with regard to two subsidiaries in the United States and the United Kingdom for which sufficient positive evidence exists, including current and projected future taxable income, that we believe it is more-likely-than-not that such 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. 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.

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, 2021 and December 31, 2020, 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.

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 and impairment 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, 2021 and 2020

	Year Ended December 31,			
	2021	2020	$ Change	% Change
		(in thousands, except percentages)		
License revenue	$ 20,376	$ —	20,376	100.0%
Operating expenses:				
Research and development	47,956	11,408	36,548	320.4%
Acquisition of in-process research and development	15,480	12,020	3,460	28.8%
General and administrative	92,745	80,734	12,011	14.9%
Total operating expenses	156,181	104,162	52,019	49.9%
Loss from operations	(135,805)	(104,162)	(31,643)	30.4%
Other income (expense), net:				
Interest income	205	71	134	188.7%
Change in fair value of contingent consideration liability - related parties	173	(1,133)	1,306	(115.3%)
Change in fair value of short term notes receivable - related party	—	718	(718)	(100%)
Change in fair value of convertible promissory notes	—	(16,974)	16,974	(100%)
Change in fair value of derivative liability	41	150	(109)	(72.7%)
Change in fair value of warrant liability	(87)	—	(87)	100.0%
Unrealized loss on other investments held at fair value	(12,346)	—	(12,346)	100.0%
Unrealized gain on other investments	—	19,856	(19,856)	(100%)
Loss on conversion of convertible promissory notes	(513)	—	(513)	100.0%
Loss on asset acquisition of a variable interest entity	—	(504)	504	(100%)
Gain on consolidation of a variable interest entity	3,543	—	3,543	100.0%
Foreign exchange gain (loss), net	8,481	(194)	8,675	(4471.6%)
Other income (expense), net	(293)	359	(652)	(181.6%)
Total other income (expense), net	(796)	2,349	(3,145)	(133.9%)
Net loss before income taxes	(136,601)	(101,813)	(34,788)	34.2%
Benefit from (provision for) income taxes	3,989	(305)	4,294	(1407.9%)
Gain on dilution of equity method investment	16,923	—	16,923	100.0%
Losses from investments in equity method investees, net of tax	(58,555)	(76,507)	17,952	(23.5%)
Net loss	(174,244)	(178,625)	4,381	(2.5%)
Net income (loss) attributable to redeemable noncontrolling interests and noncontrolling interests	(6,436)	(8,782)	2,346	(26.7%)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (167,808)	$ (169,843)	$ 2,035	-1.2%

License Revenue

License revenue was $20.4 million for the year ended December 31, 2021, which related to the Otsuka Agreement. The license revenue recognized during the year primarily relates to the delivery of the license to Otsuka, which occurred in March 2021. No license revenue was recognized for the year ended December 31, 2020.

Research and Development Expenses

The table and discussion below present research and development expenses for the years ended December 31, 2021 and 2020:

	Year Ended December 31,			
	2021	2020	Change	% Change
	(in thousands, except percentages)			
Direct research and development expenses by program:				
PCN-101 (Perception)	$ 6,862	$ 4,786	$ 2,076	43.4%
DMX-1002 (DemeRx IB)	3,583	1,396	2,187	156.7%
RL-007 (Recognify)	2,492	146	2,346	1606.8%
VLS-01 (Viridia)	2,378	—	2,378	100.0%
EMP-01 (EmpathBio Inc)	1,534	—	1,534	100.0%
KUR-101 (Kures)	1,488	2,570	(1,082)	(42.1%)
RLS-01 (Revixia)	952	—	952	100.0%
NN-01 (Neuronasal)	716	—	716	100.0%
Novel drug delivery (InnarisBio)	715	—	715	100.0%
Novel compounds (EntheogeniX)	668	497	171	34.4%
Other (Introspect, Psyber, Psyprotix)	393	—	393	100.0%
Unallocated research and development expenses:		—		
Personnel expenses	25,244	1,805	23,439	1298.6%
Professional and consulting services	451	150	301	200.8%
Other	479	58	421	721.7%
Total research and development expenses	$ 47,956	$ 11,408	$ 36,547	320.4%

Research and development expenses were $47.9 million for the year ended December 31, 2021, compared to $11.4 million for the year ended December 31, 2020. The increase of $36.5 million was primarily attributable to an increase of $23.4 million of personnel costs, which included $18.6 million in stock-based compensation and an increase of $12.4 million of direct costs at the platform companies as discussed below.

The $2.1 million increase in direct costs for PCN-101 was primarily due to an increase of $0.9 million in drug manufacturing costs, $0.6 million in clinical development costs, and $0.6 million in consulting and personnel related costs.

The $2.2 million increase in direct costs for DMX-1002 program was primarily due to an increase of $0.7 million in clinical development cost, $0.7 million in preclinical activities, $0.5 million in manufacturing, and $0.2 million increase in personnel related costs.

The $2.3 million increase in direct costs for RL-007 program was primarily due to an increase of $1.5 million in clinical development costs, $0.7 million of personnel related costs, which included $0.4 million of stock-based compensation expense and $0.2 million in manufacturing costs.

The direct costs for VLS-01 program were $2.4 million of manufacturing and control processes and other preclinical activities.

The direct costs for EMP-001 were $1.5 million of manufacturing and control processes costs and other preclinical activities.

The $1.1 million decrease in direct costs for KUR-101 was primarily due to a decrease in preclinical activities.

The direct costs for RLS-01 were $1.0 million of manufacturing and control processes costs and other preclinical activities.

The direct costs for NN-01, which are from the date of acquisition in May 2021, were $0.7 million of clinical development and personnel costs.

The direct costs for InnarisBio were $0.7 million of preclinical activities.

The $0.2 million increase is direct costs for EntheogeniX was primarily due to an increase in manufacturing and preclinical activities.

During the year ended December 31, 2021, we did not incur any significant direct costs in association with IntroSpect, Psyber, Psyprotix, TryptageniX and Invyxis ; direct costs associated with these programs were related to the ramp up of preclinical development and initial clinical-stage activities.

Acquisition of In-Process Research and Development Expense

	Year Ended December 31,			
	2021	2020	Change	% Change
	(in thousands, except percentages)			
Acquisition of in-process research and development expense by program:				
NN-01 ('Neuronasal)	$ 7,962	$ —	$ 7,962	100.0%
Biosynthesis platform (TryptageniX)	6,546	—	6,546	100.0%
Novel drug delivery (InnarisBio)	972	—	972	100.0%
KUR-101 (Kures)	—	120	(120)	(100.0%)
RL-007 (Recognify)	—	11,900	(11,900)	(100.0%)
Total acquisition of in-process research and development expense	$ 15,480	$ 12,020	$ 3,460	28.8%

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. Acquisition of in-process research and development expenses was $12.0 million for the year ended December 31, 2020, which was IPR&D acquired from Recognify and Kures. The acquired IPR&D were all considered to have no future alternative use.

General and Administrative Expenses

General and administrative expenses were $92.7 million for the year ended December 31, 2021 compared to $80.7 million for the year ended December 31, 2020 . The increase of $12.0 million was largely attributable to an increase of $25.3 million in personnel costs and professional consulting fees, a $3.4 million increase in insurance costs, a $2.9 million increase in charitable donations and sponsorships, and a $3.3 million increase in other costs related to support of our platform growth and public company requirements. These increases were partially offset by a decrease of $23.0 million in non-cash stock compensation expense. For the year ended December 31, 2020, the Company recorded stock-based compensation expense of $61.5 million in connection with the convertible notes issued in October 2020. The stock-based compensation expense included in general and administrative expense attributed to stock options and restricted stock awards was $5.4 million for the year ended December 31, 2020.

Interest Income

Interest income for the years ended December 31, 2021 and 2020 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, 2021 and 2020 of $0.2 million and $0.1 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 as of December 31, 2021, resulting in income of $0.2 million and expense of $1.1 million being recognized for the years ended December 31, 2021 and 2020, respectively. The $1.1 million of expense recognized for the year ended December 31, 2020, was primarily attributable to Perception's completion of its Phase 1 clinical trial in September 2020, which increased the probability of the milestone event occurring, and a potential license agreement with a third-party pharmaceutical company, which would include an upfront payment and additional milestone payments. For the year ended December 31, 2021, we recorded a $0.2 million income due to updates to the forecast assumptions and discount rate. There were no material changes in any of the significant assumptions used to determine the TryptageniX or InnarisBio Contentigent Consideration Liability for the year ended December 31, 2021.

Change in Fair Value of Short Term Notes Receivable—Related Party

Change in fair value of short term notes receivable with COMPASS for the year ended December 31, 2020 was $0.7 million. The COMPASS notes were converted during 2020. No change in fair value of short term notes receivable of related parties was recognized for the year ended December 31, 2021.

Change in Fair Value of Convertible Promissory Notes

Change in fair value of convertible promissory notes for the year ended December 31, 2020 was $17.0 million, which was primarily associated with the change in fair value of our 2020 convertible notes (the "2020 Notes"). The change in fair value of the 2020 Notes was

primarily attributable to an increase in the fair value of the underlying common stock in 2020 leading up to the conversion of the convertible promissory notes into our common shares in November 2020. No changes in fair value of convertible promissory notes were recognized for the year ended December 31, 2021 as the 2020 Notes were converted into our common shares in November 2020.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability was $41,000 for the year ended December 31, 2021, compared to $0.2 million for the year ended December 31, 2020. The $0.1 million increase was primarily due to the additional issuance of convertible promissory notes in January 2021 and the increased probability of a potential licensing transaction with a third-party pharmaceutical company and a decrease in the probability of a potential preferred equity financing round.

Change in Warrant Liability

Change in fair value of warrant liability was $87,000 for the year ended December 31, 2021. The warrant liability was recorded in connection with issued and outstanding warrants to purchase shares of Neuronasal's common stock acquired in connection with the acquisition of Neuronasal. The warrant liability was recorded in connection with the May 2021 acquisition of Neuronasal.

Unrealized Loss on Other Investments Held at Fair Value

In May 2021, we received IntelGenx common shares, 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 the consolidated statements of operations. Subsequently, changes in fair value of the common shares, the warrants and additional unit warrants are recorded as a component of other income (expense), net in the consolidated statement of operations. During the year ended December 31, 2021, we recognized $12.3 million of unrealized loss on other investments held at fair value.

Unrealized Gain on Other Investments

Unrealized gain on other investments for the year ended December 31, 2021 was zero compared to $19.9 million for the year ended December 31, 2020. The $19.9 million gain in 2020 mainly related to our remeasurement of our investment in COMPASS' Series A preferred shares to fair value due to the observable price change in connection with the purchase of COMPASS' Series A preferred stock in March 2020.

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 license and collaborative 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, 2020.

Loss on Asset Acquisition of a Variable Interest Entity

We did not incur loss on asset acquisition of a variable interest entity during the year ended December 31, 2021. Loss on asset acquisition of a variable interest entity was $0.5 million for the year ended December 31, 2020. This loss was related to our acquisition of Recognify in November 2020.

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, 2020.

Foreign Exchange Gain (Loss), Net

Foreign exchange gain (loss), net was a gain of $8.5 million for the year ended December 31, 2021 compared to a loss of $0.2 million for the year ended December 31, 2020. The increase of $8.5 million was 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 Income (Expense), Net

Other expense, net for the year ended December 31, 2021 was $0.3 million, compared to other income, net, of $0.4 million for the year ended December 31, 2020. The decrease of $0.7 million was primarily related to interest expense.

Benefit From (Provision For) Income Taxes

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. We incurred $0.3 million of current income tax expense for the year ended December 31, 2020. Our current income tax expense relates to book profits and thus taxable profits generated in one of our United States subsidiaries and our United Kingdom subsidiary. The deferred income tax benefit relates to deferred tax assets generated in the year ended December 31, 2021 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, with the exception of those previously noted, primarily related to German and international tax loss carryforwards 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.

Losses from Investments in Equity Method Investees

Losses from investment in equity method investees for the years ended December 31, 2021 and 2020 were $58.6 million and $76.5 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

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. Since our inception through December 31, 2021, sources of capital raised to fund our operations were comprised of aggregate gross proceeds of $630.0 million from sales of our common shares and convertible notes. As of December 31, 2021, we had cash and cash equivalents of $362.3 million.

Convertible Promissory Notes

In November 2018, we issued an aggregate principal amount of $0.2 million of convertible notes, or 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. In September and October 2021, several investors agreed to convert their 2018 Convertible Notes into shares of ATAI Life Sciences N.V. and paid an aggregate amount of €5.8 million ($6.9 million). 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 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 convertible promissory notes balance as of December 31, 2021 was $0.7 million.

Investments

While a significant potential source of liquidity resides in our investment in COMPASS ordinary 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 $211.4 million as of December 31, 2021. As of December 31, 2021, the carrying value of our investment in COMPASS was $16.1 million under the equity method. Through a series of open market transactions between November 23, 2021 and December 7, 2021 the Company purchased additional equity investments in COMPASS common stock. From the time of the additional investment through December 31, 2021, our voting interest in COMPASS was 22.8%.

Liquidity Risks

As of December 31, 2021, we had cash and cash equivalents of $362.3 million. We believe that our cash and cash equivalents will be sufficient to fund our projected operating expenses and capital expenditures through at least the next 12 months from the date of this Form 10-K.

We expect to incur substantial additional expenditures in the near term to support our ongoing activities. Additionally, we expect 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 atai companies upon the achievement of specified development milestone events;
- the cash requirements for developing our programs and our ability and willingness to finance their continued development;
- the cash requirements for any future acquisitions or discovery of product candidates; and
- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies and other strategic transactions. We do not currently have any committed external source of funds. 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, 2021 and 2020:

	December 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (63,246)	$ (20,766)
Net cash used in investing activities	(81,276)	(28,271)
Net cash provided by financing activities	409,862	113,052
Effect of foreign exchange rate changes on cash	(320)	3,169
Net increase (decrease) in cash	$ 265,020	$ 67,184

Net Cash Used in Operating Activities

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 operating activities was $20.8 million in the year ended December 31, 2020, which consisted of a net loss of $178.6 million, adjusted by non-cash charges of $153.5 million and net cash outflows from the change in operating assets and liabilities of $4.4 million. The non-cash charges primarily consisted of $76.5 million of losses from our equity method investments, $67.2 million related to our stock-based compensation, including the non-cash compensation expense of $61.5 million in connection with our convertible notes issued in October 2020 to related parties, $17.0 million of changes in fair value related to our convertible promissory note, $12.0 million of IPR&D considered to have no future alternative use and partially offset by $19.9 million of unrealized gains on our other investments. The net cash outflows from the change in operating assets and liabilities were primarily due to a $3.9 million increase in accrued and other liabilities and a $1.7 million increase in accounts payable, partially offset by a $1.2 million increase in prepaid expenses driven by materials and non-clinical trials.

Net Cash Used in Investing Activities

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 used in investing activities was $28.3 million for the year ended December 31, 2020, primarily driven by additional investments of $23.9 million in our other investments, $2.1 million of payments made for investments in GABA and Neuronasal accounted for under the equity method, $1.9 million of purchases of long-term notes receivable in connection with loans made to DemeRx, Inc. and a COMPASS shareholder of $1.0 million and $0.9 million, respectively, and $0.2 million of purchases of a short-term notes receivable in relation to a loan made to a related party.

Net Cash Provided by Financing Activities

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.

Net cash provided by financing activities was $113.1 million in the year ended December 31, 2020, primarily due to $82.4 million of net proceeds from the issuance of our common shares, $31.4 million of proceeds from the issuance of convertible promissory notes, including convertible promissory notes issued to related parties, and $1.0 million of net proceeds from the issuance of Perception's convertible promissory note.

Indebtedness

Convertible Notes

Between November 2018 and December 2021, we issued an aggregate of $34.3 million of convertible notes.

In November 2018, we issued an aggregate principal amount of $0.2 million of convertible notes, or 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 September and October 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. 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, 2021 an aggregate principal amount of $0.7 million remaining outstanding under the 2018 Convertible Notes.

During the year ended December 31, 2020, we issued an aggregate of $30.4 million of the 2020 Notes. The 2020 Notes accrue interest at a rate of 5% per annum and have a maturity date of January 31, 2022, unless previously redeemed, converted, purchased or cancelled. The 2020 Notes are convertible upon mandatory conversion events into shares of ATAI Life Sciences N.V., subject to certain dilution adjustments. In November 2020, all of the outstanding principal and accrued interest under the 2020 Notes was automatically converted into shares of common stock.

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 licensing and collaboration arrangement between Perception and Otsuka Pharmaceutical Co., LTD.

Promissory Note

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, or the DemeRx IB SPA, to make aggregate payments to DemeRx IB of up to $17.0 million upon the achievement of specified clinical and regulatory milestones. As of December 31, 2021, we had made aggregate payments of $15.0 million pursuant to the DemeRx IB SPA.

Investment in Convertible Promissory Notes—Related Party

On September 27, 2019, we purchased convertible promissory notes from COMPASS for an aggregate principal amount of $4.0 million, and on November 6, 2019, we purchased an additional convertible promissory note for $4.2 million, together, the COMPASS Notes. The COMPASS Notes bear interest at an annual rate of 3%, which was considered contingent in nature and therefore no earned interest was

recorded. We qualified for and elected the fair value option. All principal amounts under the COMPASS Notes were converted into shares of COMPASS Series B preferred stock in connection with COMPASS' sale of Series B preferred stock in April 2020.

On March 16, 2020, Perception Neuroscience entered into a convertible promissory note agreement with us and certain other unrelated investors, or the Perception Note Purchase Agreement, pursuant to which Perception Neuroscience issued $3.9 million in principal amount of convertible notes in aggregate. Under the Perception Note Purchase Agreement, Perception Neuroscience issued convertible notes, or the Perception Notes, in the aggregate principal amount of $3.3 million to us and $0.6 million to other investors, including related parties. The Perception Notes bear interest at an annual rate of 5% and are due and payable on June 30, 2022 unless earlier converted. In December 2020, Perception Neuroscience issued additional convertible notes to us, certain related parties and third party investors in the 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 Perception Note Purchase Agreement, Perception issued 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 Neuroscience issued additional convertible notes to us, certain related parties and third party investors in the 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 notes bear interest at an annual rate of 5% and are due and payable on February 28, 2022, unless earlier converted. Perception Neuroscience may not prepay in whole or in part without our consent.

In June 2021, Perception received proceeds of $20.0 million pursuant to the licensing and collaboration arrangement between Perception and Otsuka Pharmaceutical Co., LTD. Upon receipt of the proceeds, the convertible promissory notes automatically converted into 6,456,595 shares of Series A preferred stock of Perception pursuant to their original terms.

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 Form 10-K. 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 Form 10-K.

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.

As of December 31, 2021, we had made aggregate payments of $0.3 million pursuant to the Chiba License Agreement.

GABA Preferred Stock Purchase Agreement

We entered into the Preferred Stock Purchase Agreement, or the GABA PSPA, in August 2019 with GABA Therapeutics LLC, and purchased shares of Series A preferred stock of GABA at a price of approximately $5.5 million. In addition, pursuant to the GABA PSPA, we are obligated to purchase additional shares of Series A preferred stock, at the same price as the original transaction, for up to $10.0 million, upon the achievement of specified contingent development milestones.

In October 2020, we entered into an Omnibus Amendment Agreement, or the GABA Omnibus Amendment Agreement, with GABA and GABA Therapeutics LLC under which the Right of First Refusal and Co-Sale Agreement was amended. Pursuant to the GABA Omnibus

Amendment, GABA Therapeutics LLC granted us the right to purchase additional shares of common stock of GABA held by GABA Therapeutics LLC at the call option purchase price of $1.8 million. In November 2020, we exercised the call option and made a cash contribution of $1.8 million in exchange for additional shares of common stock of GABA.

In April 2021, pursuant to the GABA PSPA, we purchased additional shares of Series A preferred stock of GABA for an aggregate cost of $5.0 million based on the achievement of certain development milestones.

In May 2021, we purchased additional shares of Series A preferred stock prior to the achievement of certain development milestones for an aggregate cost of $5.0 million. The GABA PSPA terminates upon the occurrence of certain liquidation events.

In May 2021, we, GABA and GABA Therapeutics LLC entered into an Amendment Agreement under which the GABA PSPA was amended. Pursuant to the Amendment Agreement, we purchased additional shares of GABA Series A preferred stock at a price of approximately $0.6 million. We are obligated to purchase additional shares of GABA Series A preferred stock for up to $1.5 million with the same price per share as our initial investment upon the achievement of specified contingent development milestones.

Further in accordance with the GABA PSPA, we have 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 of the specified milestones. Additionally, we have the Right of First Refusal and Co-Sale Agreement with GABA Therapeutics LLC, under which we have the option but not the obligation to purchase shares of common stock for up to $2.0 million from the existing common shareholders.

As of December 31, 2021, we had made aggregate payments of $15.5 million pursuant to the GABA PSPA, $1.8 million pursuant to the GABA Omnibus Amendment Agreement and $0.6 million pursuant to the Amendment Agreement.

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.

As of December 31 2021, we had made no material payments pursuant to the Allergan License agreement.

Columbia Stock Purchase Agreement

In June 2020, Kures and Columbia entered into a stock purchase agreement, or the Kures SPA. Pursuant to the Kures SPA, Kures can, from time to time, 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, and shall be deemed to have been paid in partial consideration for the execution, delivery and performance by Columbia of the Kures License Agreement. If Kures proposes to sell any equity securities or securities convertible into equity securities, Columbia will have the right to purchase up to 5% of such securities. These rights shall terminate upon the occurrence of an IPO, if Kures becomes subject to periodic reporting requirements under Section 12(g) or 15(d) of the Exchange Act or certain liquidation events. Columbia also has certain co-sale rights. At the acquisition date, we recorded the fair value of the shares of Kures common stock issued to Columbia of $0.1 million to our additional-paid-in-capital and a debit to research and development expense.

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. 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 2021, 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 with Dalriada Drug Discovery Inc., or Dalriada. Under the Invyxis exclusive services and 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.

As of December 31, 2021, we had made no payments pursuant to the Dalriada License agreement.

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 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 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

We evaluate each of our 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, 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, 2021 and 2020, 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 in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date.

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. 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.

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 initial public offering, 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, 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.

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.

As described in Note 2 to our consolidated financial statements included elsewhere in this Form 10-K, we have 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. 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.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, or December 31, 2026, (b) in which we have total annual gross revenues of $1.07 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common shares held by non-affiliates equal or exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

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.

Interest Rate Sensitivity

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, 2021, we had cash and cash equivalents of $362.3 million. We generally hold our cash in interest-bearing demand deposit accounts. Due to the nature of our cash, 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 do not enter into investments for trading or speculative purposes.

As of December 31, 2021, we had $0.8 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, 2021, the carrying amount of our short and long-term notes receivables was an aggregate amount of $4.7 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.

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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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

Parsippany, New Jersey
March 30, 2022

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,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 362,266	$ 97,246
Prepaid expenses and other current assets	11,903	2,076
Short term notes receivable	913	—
Short term notes receivable - related party	—	226
Total current assets	375,082	99,548
Property and equipment, net	149	71
Deferred offering costs	—	1,575
Equity method investments	16,131	—
Other investments	11,628	8,044
Long term notes receivable	—	911
Long term notes receivable - related parties	3,835	1,060
Other assets	7,341	339
Total assets	$ 414,166	$ 111,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	6,004	3,083
Accrued liabilities	14,829	9,215
Current portion of contingent consideration liability - related parties	51	—
Other current liabilities	51	—
Total current liabilities	20,935	12,298
Non-current portion of contingent consideration liability - related parties	2,432	1,705
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	743	1,199
Convertible promissory notes and derivative liability (including a related party convertible promissory note and derivative liability of $0 million and $0.3 million at December 31, 2021 and December 31, 2020, respectively)	—	978
Other liabilities	4,097	—
Total liabilities	28,207	16,180
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, €0.10 par value ($0.12 par value at December 31, 2021 and December 31, 2020, respectively); 750,000,000 and 173,116,704 shares authorized at December 31, 2021 and December 31, 2020, respectively; 160,677,001 and 114,735,712 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	18,002	13,372
Additional paid-in capital	725,045	261,626
Accumulated other comprehensive income (loss)	(8,336)	5,819
Accumulated deficit	(357,803)	(189,995)
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	376,908	90,822
Noncontrolling interests	9,051	4,546
Total stockholders' equity	385,959	95,368
Total liabilities and stockholders' equity	$ 414,166	$ 111,548

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)

	Year Ended December 31,	
	2021	2020
License revenue	$ 20,376	$ —
Operating expenses:		
Research and development	47,956	11,408
Acquisition of in-process research and development	15,480	12,020
General and administrative	92,745	80,734
Total operating expenses	156,181	104,162
Loss from operations	(135,805)	(104,162)
Other income (expense), net:		
Interest income	205	71
Change in fair value of contingent consideration liability - related parties	173	(1,133)
Change in fair value of short term notes receivable - related party	—	718
Change in fair value of convertible promissory notes	—	(16,974)
Change in fair value of derivative liability	41	150
Change in fair value of warrant liability	(87)	—
Unrealized loss on other investments held at fair value	(12,346)	—
Unrealized gain on other investments	—	19,856
Loss on conversion of convertible promissory notes	(513)	—
Loss on asset acquisition of a variable interest entity	—	(504)
Gain on consolidation of a variable interest entity	3,543	—
Foreign exchange gain (loss), net	8,481	(194)
Other income (expense), net	(293)	359
Total other income (expense), net	(796)	2,349
Net income (loss) before income taxes	(136,601)	(101,813)
Benefit from (provision for) income taxes	3,989	(305)
Gain on dilution of equity method investment, net of tax	16,923	—
Losses from investments in equity method investees, net of tax	(58,555)	(76,507)
Net loss	(174,244)	(178,625)
Net income (loss) attributable to redeemable noncontrolling interests and noncontrolling interests	(6,436)	(8,782)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (167,808)	$ (169,843)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (1.21)	$ (1.83)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	138,265,859	93,019,072

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2021	2020
Net loss	$ (174,244)	$ (178,625)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	(14,155)	7,245
Comprehensive income (loss)	$ (188,399)	$ (171,380)
Comprehensive income (loss) attributable to redeemable noncontrolling interests and noncontrolling interests	(6,436)	(8,782)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests	(24)	(13)
Comprehensive loss attributable to redeemable noncontrolling interests and noncontrolling interests	(6,460)	(8,795)
Comprehensive income (loss) attributable to ATAI Life Sciences N.V. stockholders	$ (181,939)	$ (162,585)

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 Income (Loss)	Accumulated Deficit	Total Stockholders' Equity Attributable to ATAI Life Sciences N.V. Stockholders	Noncontrolling Interests	Total Stockholders' Equity
Balances at December 31, 2019	$ 142	90,709,312	$ 10,510	$ 69,819	$ —	$ (1,426)	$ (20,152)	$ 58,751	$ 887	$ 59,638
Issuance of common shares, net of issuance costs of $5.2 million	—	14,933,344	1,756	75,456	—	—	—	77,212	—	77,212
Exercise of stock options	—	320,000	38	82	—	—	—	120	—	120
Issuance of common shares in connection with the conversion of 2020 Convertible Promissory Notes (Note 11)	—	8,773,056	1,068	48,991	—	—	—	50,059	—	50,059
Issuance of noncontrolling interest	—	—	—	—	—	—	—	—	12,312	12,312
Issuance of subsidiary shares in connection with the Columbia stock purchase agreement (Note 17)	—	—	—	120	—	—	—	120	—	120
Stock-based compensation expense	—	—	—	67,158	—	—	—	67,158	—	67,158
Foreign currency translation adjustment, net of tax	—	—	—	—	—	7,245	—	7,245	(13)	7,232
Net income (loss)	(142)	—	—	—	—	—	(169,843)	(169,843)	(8,640)	(178,483)
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

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (174,244)	$ (178,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	47	24
Amortization of debt discount	195	64
Change in fair value of contingent consideration liability- related parties	(173)	1,133
Change in fair value of short term notes receivable - related parties	—	(718)
Change in fair value of convertible promissory notes	—	16,974
Change in fair value of derivative liability	(41)	(150)
Change in fair value of warrant liability	87	—
Unrealized loss on other investments held at fair value	12,346	—
Unrealized gains on other investments	—	(19,856)
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)	—
Loss on asset acquisition of a variable interest entity	—	504
Losses from investments in equity method investees	58,555	76,507
In-process research and development expense	15,480	12,020
Stock-based compensation expense	63,362	67,158
Unrealized foreign exchange gains	(11,346)	(155)
Other	43	(96)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(9,699)	(1,150)
Other assets	(5,973)	—
Accounts payable	2,300	1,704
Accrued liabilities	5,756	3,896
Deferred revenue	12	—
Net cash used in operating activities	(63,246)	(20,766)
Cash flows from investing activities		
Purchases of property and equipment	(173)	(59)
Capitalized internal-use software development costs	(955)	—
Cash acquired in asset acquisitions, net	47	276
Cash paid for asset acquisitions, net	(1,000)	—
Cash paid for equity method investments	(52,937)	(2,088)
Cash paid for other investments	(11,312)	(23,920)
Cash paid for other investments held at fair value	(12,346)	—
Purchases of short-term notes receivable—related party	—	(226)
Purchases of long term notes receivable	—	(1,916)
Loans to related parties	(2,600)	—
Other	—	(338)
Net cash used in investing activities	(81,276)	(28,271)
Cash flows from financing activities		
Proceeds from issuance of common stock	409,884	82,439
Cash paid for common stock issuance costs	(12,350)	(1,314)
Purchase of noncontrolling interest	—	—
Cash paid for deferred offering costs	—	(696)
Proceeds from issuance of share option awards	534	—
Proceeds from sale of investment	2,417	—
Proceeds from issuance of convertible promissory notes—related parties	—	1,022
Proceeds from issuance of convertible promissory notes	—	30,437
Proceeds from the issuance of convertible promissory notes (including proceeds from a related party convertible promissory note of $0.3 million for 2020)	1,588	1,044
Exercise of stock options	935	120
Proceeds from conversion of convertible notes to common stock	6,854	—
Net cash provided by financing activities	409,862	113,052
Effect of foreign exchange rate changes on cash	(320)	3,169
Net increase (decrease) in cash and cash equivalents	265,020	67,184
Cash and cash equivalents – beginning of the period	97,246	30,062
Cash and cash equivalents – end of the period	$ 362,266	$ 97,246
Supplemental disclosures of non-cash investing and financing information:		
Common stock issuance costs in accounts payable	$ —	$ 94
Common stock issuance costs in accrued liabilities	$ —	$ 3,819
Conversion of short term notes receivable for other investments	$ —	$ 9,003
Conversion of other investments into equity method investments	$ —	$ 53,101
Deferred offering costs in accounts payable	$ —	$ 358
Deferred offering costs in accrued liabilities	$ —	$ 468
Fair value of noncontrolling interests issued in connection with asset acquisitions	$ 4,761	$ 12,312
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	$ —
Issuance of common shares in connection with the conversion of convertible promissory notes	$ —	$ 50,059
Issuance of subsidiary shares in connection with a stock purchase agreement	$ —	$ 120
Issuance of subsidiary shares in connection with the conversion of convertible notes	$ 3,258	$ —
Exercise of Hurdle Share Option Plan award	$ 527	$ —
Issuance of derivative instrument related to convertible promissory notes	$ 646	$ 364

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 stock on the Nasdaq Stock Market ("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 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 twelve months ended December 31, 2021. 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 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. For a discussion of the risks to the Company's business from COVID-19, refer to the section titled "Risk Factors" in Part I, Item 1A.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2021, the Company had cash and cash equivalents of $362.3 million and its accumulated deficit was $357.8 million. The Company has historically financed its operations through the sale of equity securities, 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 as of December 31, 2021 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"). 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.

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 short term notes receivable—related party with COMPASS Pathways plc, investment in Intelgenx Technologies Corp. ("IntelGenx"), warrant liability with Neuronasal Inc., convertible promissory notes issued in connection with the 2020 convertible note agreement (the "2020 Convertible Notes"), contingent consideration liability—related parties, derivative liability associated with the Perception convertible promissory notes, in-process research and development assets ("IPRD"), 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, 2021 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, 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 deemed to be limited based on the Company's evaluation and monitoring of the liquidity and capital resources of the counterparties. 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.

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).

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, 2021 and 2020, 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 in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date.

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, 2021 and December 31, 2020, cash and cash equivalents consisted of cash on deposit and cash held in high-yield savings accounts and money market funds.

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 in-process research and development (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, 2021 and 2020.

Other Investments Held at Fair Value

As permitted under Accounting Standards Codification 825, Financial Instruments, or ASC 825, the Company has elected the fair value option to account for its investment in 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 the 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.

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, 2021, 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 12 months from the balance sheet date.

Fair Value Option

The Company has also elected the fair value option to account for its short term notes receivable—related party with COMPASS Pathways plc and the 2020 Convertible Notes. In accordance with ASC 825, the Company records the short term notes receivable - related party with COMPASS Pathways plc and the 2020 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. The 2020 Convertible Notes converted into common shares of atai in November 2020. The short term notes receivable—related party with COMPASS Pathways plc converted into COMPASS common shares, which were exchanged for American Depository Shares in September 2020.

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 and Derivative Instruments

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 have been 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, 2021.

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 R&D.

Warrant Liability

The Company accounts for its warrant liabilities in accordance with the guidance contained in ASC 815-40 under which the warrants do not meet the criteria for equity treatment and therefore must be recorded as liabilities. Warrants are included in other liabilities in the consolidated balance sheet. The warrants are recorded at fair value and subsequently remeasured to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income (expense), net in the consolidated statements of operations.

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.

The expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. 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, 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, investment in common shares of IntelGenx, IntelGenx Initial Warrants and Additional Units Warrant, 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, 2021, the carrying amount and fair value amount of the 2018 Convertible Notes was $0.8 million and $69.7 million, respectively. As of December 31, 2020, the carrying amount and fair value amount of the 2018 Convertible Notes was $1.2 million and $76.7 million, respectively. Subsequent to the IPO, several noteholders of the 2018 Convertible Notes elected to convert their promissory notes into shares of the Company's common stock. 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, 2021, there were no Perception convertible promissory notes outstanding. As of December 31, 2020, the carrying amount and fair value amount for Perception convertible promissory notes was $0.8 million and $4.6 million, respectively. 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 August 2020, the FASB issued ASU 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815—40)" ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. The ASU's amendments are effective for the Company for fiscal years beginning after December 15, 2023 and interim periods within those fiscal years, with early adoption permitted. The Company early adopted this standard on January 1, 2021 applying the modified retrospective transition approach. Upon adoption of ASU 2020-06, the embedded conversion option related to the 2018 Convertible Notes is no longer separated from the host contract and recognized within additional paid-in-capital and is instead accounted for as a single liability measured at amortized cost within convertible promissory notes—related parties in the consolidated balance sheets. Therefore, the unamortized debt discount of $8,000 was eliminated.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," or ASU No. 2016-02, which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. 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. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-11 Leases – Targeted Improvements, or ASU 2018-11, intended to ease the implementation of the new lease standard for financial statement preparers by, among other things, allowing for an additional transition method. In lieu of presenting transition requirements to comparative periods, as previously required, an entity may now elect to show a cumulative effect adjustment on the date of adoption without the requirement to recast prior period financial statements or disclosures presented in accordance with ASU 2016-02.

The new standard provides a number of optional practical expedients in transition. We expect to elect the 'package of practical expedients', which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. We do not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us.

While we continue to assess all of the effects of adoption, we currently believe the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on our balance sheet for our real estate operating leases and (2) providing significant new disclosures for our leasing activities.

The new standard also provides practical expedients and certain exemptions for an entity's ongoing accounting. We currently expect to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also currently expect to elect the practical expedient to not separate lease and non-lease components for all of our leases.

We have determined the completeness of our lease population as of January 1, 2022. We expect to complete our assessment of the full financial impact of ASC 842 during the first quarter of 2022, and will include all required presentation and disclosures under ASC 842 in our Form 10-Q for the three months ending March 31, 2022.

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 such, ASU 2016-13 is effective for the Company beginning after December 15, 2022. The Company is currently assessing the impact of the adoption of this ASU on its consolidated financial statements.

3. Acquisitions

2020 Acquisition

Recognify Life Sciences, Inc.

Recognify Life Sciences Inc. ("Recognify") (previously known as FSV7, Inc.) is developing a Phase II-ready asset, previously tested in 9 clinical trials in over 500 subjects, which preliminarily exhibited pro-cognitive effects on exploratory endpoints in pain patients as well as in two volunteer trials involving experimental cognitive paradigms. On November 6, 2020, pursuant to a Series A Preferred Stock Purchase Agreement (the "Recognify Purchase Agreement"), the Company acquired shares of Recognify's Series A preferred stock in exchange for an initial payment of $2.0 million in cash. In addition, pursuant to the Recognify Purchase Agreement, the Company agreed to make aggregate payments to Recognify of up to $18.0 million upon the achievement of specified clinical and regulatory milestones to complete the purchase of the shares and provide additional funding to Recognify. The Recognify Purchase Agreement resulted in the Company holding a 51.9% voting interest in Recognify. In connection with the Company's agreement for additional funding, Recognify issued the corresponding Series A preferred shares to the Company provided that the shares are held in an escrow account (the "Escrow Shares"). The Escrow Shares will be released, from time to time, to the Company upon Recognify achieving certain milestones as defined in the Recognify 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 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, a pro rata portion of the Escrow Shares will automatically be surrendered and be deemed forfeited and canceled, and could result in the Company losing control of Recognify's board of directors and its controlling financial interest in Recognify.

In addition, the Recognify Purchase Agreement provided the Company unilateral rights to control all decisions related to the significant activities of Recognify. The Company concluded that Recognify was not considered a business based on its assessment under ASC 805 and accounted for the Company's acquisition in Recognify 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 loss of $0.5 million. The loss was calculated as the sum of the consideration paid of $2.0 million, the fair value of the noncontrolling interest issued of $12.3 million, less the fair value of identifiable net assets acquired of $13.8 million. The fair value of the IPR&D acquired of $11.9 million was charged to research and development expense as it had no alternative future use at the time of the acquisition.

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, 2021, 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 twelve months 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.

In July 2021, pursuant to the Psyber Purchase Agreement discussed above, the Company released a payment in the amount of $0.7 million upon the achievement of specified clinical milestones. Accordingly, 2,437,500 Series A Preferred Stock was released from the escrow account to atai. The Company's equity ownership interest in Psyber remained unchanged as the Psyber Escrow Shares were already deemed issued, outstanding and legally owned by atai.

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 twelve months 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 twelve months ended December 31, 2021 as it had no alternative future use at the time of the acquisition.

In November 2021, pursuant to the InnarisBio Purchase Agreement discussed above, the Company released a payment in the amount of $1.2 million upon the achievement of specified clinical milestones. Accordingly, 1,238,000 Series A Preferred Stock was released from the escrow account to atai. The Company's equity ownership interest in InnarisBio remained unchanged as the InnarisBio Escrow Shares were already deemed issued, outstanding and legally owned by atai.

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.

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. For the acquisitions further described in Note 3, the Company determined that Recognify Life Sciences, Inc., PsyProtix, Inc., Psyber, Inc., InnarisBio, Inc., Neuronasal, Inc., and TryptageniX Inc. are VIEs as each entity does not have sufficient equity at risk to carry out its principal activities without additional subordinated financial support.

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, 2021.

As of December 31, 2021 and December 31, 2020, the Company has accounted for the following consolidated investments as VIEs, excluding the wholly owned subsidiaries:

Consolidated Entities	Relationship as of December 31, 2021	Relationship as of December 31, 2020	Date Control Obtained	Ownership % December 31, 2021	Ownership % December 31, 2020
Perception Neuroscience Holdings, Inc.	Controlled VIE	Controlled VIE	November 2018	58.9%	50.1%
Kures, Inc.	Controlled VIE	Controlled VIE	August 2019	54.1%	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	—	February 2021	75.0%	—
Psyber, Inc.	Controlled VIE	—	February 2021	75.0%	—
InnarisBio, Inc.	Controlled VIE	—	March 2021	82.0%	—
Neuronasal, Inc.	Controlled VIE	Investment	May 2021	56.5%	37.2%
TryptageniX Inc.	Controlled VIE	—	December 2021	65.0%	—

As of December 31, 2021 and December 31, 2020, 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 500,000 shares of Class A common stock for an aggregate purchase price of $0.5 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, 2021 and December 31, 2020, 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, 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

The following table presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) for all consolidated VIEs as of December 31, 2020 (in thousands):

	Perception	Kures	EntheogeniX	DemeRx IB	Recognify
Assets:					
Current assets:					
Cash	$ 6,527	$ 1,264	$ 652	$ 7,252	$ 1,895
Prepaid expenses and other current assets	768	124	—	193	44
Total current assets	7,295	1,388	652	7,445	1,939
Property and equipment, net	4	—	—	—	—
Long term notes receivable	—	—	—	1,060	—
Total assets	$ 7,299	$ 1,388	$ 652	$ 8,505	$ 1,939
Liabilities:					
Current liabilities:					
Accounts payable	$ 564	$ 220	$ 35	$ 230	$ 64
Accrued liabilities	297	229	11	92	66
Total current liabilities	861	449	46	322	130
Convertible promissory notes and derivative liability	978	—	—	—	—
Contingent consideration liability	1,705	—	—	—	—
Total liabilities	$ 3,544	$ 449	$ 46	$ 322	$ 130

Noncontrolling Interests

The Company recognizes noncontrolling interests related to its consolidated VIEs and provides a rollforward of the noncontrolling interests balance, as follows (in thousands):

	Perception	Kures	Recognify	Psyber	InnarisBio	Neuronasal	TryptageniX	Total
Balance as of December 31, 2019	$ 487	$ 400	$ —	$ —	$ —	$ —	$ —	$ 887
Issuance of noncontrolling interests	—	—	12,312	—	—	—	—	12,312
Net income (loss) attributable to noncontrolling interests - common	—	—	(6,508)	—	—	—	—	(6,508)
Net income (loss) attributable to noncontrolling interests - preferred	(474)	(400)	(1,258)	—	—	—	—	(2,132)
Comprehensive loss attributable to noncontrolling interests	(13)	—	—	—	—	—	—	(13)
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

Redeemable Noncontrolling Interests

In connection with the consolidation of 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.

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, 2021 and December 31, 2020, 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, 2021 and December 31, 2020, the balance of redeemable noncontrolling interests in temporary equity on the consolidated balance sheets was zero.

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

	Kures	Neuronasal	Total
Balance as of December 31, 2019	$ 142	$ —	$ 142
Net loss attributable to redeemable noncontrolling interests - preferred	(142)	—	(142)
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 and a VOEs

The Company evaluated the nature of its investments in Innoplexus AG ("Innoplexus") and DemeRx NB, Inc. ("DemeRx NB") and determined that the investments are VIEs as of the date of the Company's initial investment through December 31, 2021. 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, 2021 and December 31, 2020.

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, 2021, the Company's maximum exposure for its non-consolidated VIEs was $11.6 million relating to the carrying values in other investments and other investments held at fair value and $3.8 million relating to the carrying value in long term notes receivable – related party. As of December 31, 2020, the Company's maximum exposure for its non-consolidated VIEs was $8.0 million relating to the carrying values in its other investments and $0.2 million relating to the carrying value in short term notes receivable—related party.

The Company evaluated the nature of its investment in GABA Therapeutics, Inc. ("GABA") and determined that GABA was a VIE through May 21, 2021 when the Company exercised its option to purchase additional shares of Series A Preferred stock for an aggregate purchase price of $5.0 million (see Note 5). Prior to the option exercise, the Company was not the primary beneficiary as it did not have the power to direct the activities that most significantly impact the investment's economic performance and therefore concluded that it did not

have a controlling financial interest that would require consolidation through May 21, 2021. 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 (See Note 5).

As disclosed in Note 5, as of December 31, 2021, the Company is obligated to purchase additional shares of Series A preferred stock of GABA for up to $1.5 million upon the achievement of certain specified contingent clinical development milestones.

The Company had an investment in COMPASS Pathways plc (formerly known as Compass Pathfinder Holding Limited) ("COMPASS") which was determined to be an investment in a VIE as of December 31, 2019 and through the date prior to its initial public offering in September 2020 ("COMPASS IPO"); however, the Company was not the primary beneficiary as it did not have the power to direct the activities that most significantly impact the investment's economic performance and therefore concluded that it did not have a controlling financial interest that would require consolidation during the period between December 31, 2019 and through September 2020. The completion of the COMPASS IPO in September 2020 was deemed to be a reconsideration event. Upon the completion of the COMPASS IPO, the Company's investment in COMPASS was no longer deemed an investment in a VIE as COMPASS now had sufficient equity at risk to finance its activities 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. From the date of the COMPASS IPO through December 31, 2020, the Company's voting interest was 26.3% which included the voting rights provided under the voting agreements as further described in Note 5 below. In April 2021, the voting agreements were terminated. On May 4, 2021, the Company purchased additional equity investments in COMPASS common stock in connection with a secondary equity offering, after which, the Company's voting interest was 19.7%. Subsequently through a series of open market transactions between November 23, 2021 and December 7, 2021 the Company purchased additional equity investments in COMPASS common stock. From the time of the additional investment through December 31, 2021, the Company's voting interest was 22.8%. The Company concluded that it did not have a controlling financial interest that would require consolidation under the VOE model and accounted for the investments in COMPASS common stock under the equity method (See Note 5).

5. Equity Method Investments and Other Investments

Equity Method Investments

As of December 31, 2021 and December 31, 2020, the Company accounted for the following investments in the investee's common stock under the equity method (amounts in thousands):

		As of December 31, 2021			As of December 31, 2020		
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[2]	December 2018	22.8%		16,131	22.1%		—
GABA Therapeutics, Inc	November 2020	7.5%	(1)	—	7.5%	(1)	—
Neuronasal, Inc	October 2020	N/A	(3)	—	9.8%	(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.

(2) Prior to the consummation of the COMPASS IPO in September 2020, COMPASS undertook a corporate reorganization. As part of the corporate reorganization, COMPASS became a wholly owned subsidiary of COMPASS Rx Limited. COMPASS Rx Limited was re-registered as a public limited company and renamed COMPASS Pathways plc.
(3) Neuronasal common stock was accounted for under the equity method until the entity was consolidated on May 17, 2021 (See Note 3).

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, 2021 and December 31, 2020, 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, 2021	December 31, 2020
GABA Therapeutics, Inc.	$ 10,260	$ 5,519
DemeRx NB, Inc.	1,024	1,096
Juvenescence Limited	344	368
Neuronasal, Inc.	—	1,061
Total	$ 11,628	$ 8,044

The Company's investments in the preferred stock of COMPASS though the date of its IPO in September 2020, Neuronasal (through May 2021), 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, 2021 and 2020 there were no observable changes in price recorded related to the Company's Other Investments.

During the years ended December 31, 2021 and 2020, the Company evaluated all of its other investments to determine if certain events or changes in circumstance during these time periods in 2021 and 2020 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 were reflected as a secured borrowing liability of $2.4 million as of December 31, 2021, which is included in Other liabilities in the Company's consolidated balance sheet. 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, 2021.

The carrying value of the Company's investment in Innoplexus was zero as of December 31, 2021 and December 31, 2020.

COMPASS Pathways plc

COMPASS Pathways plc 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

During the first quarter of 2020, the Company's investment in COMPASS common stock, which was accounted for under the equity method, was reduced to zero after the Company recognized its proportionate share of COMPASS' net loss from investments in equity method investees. Immediately prior to the completion of the COMPASS IPO, the different classes of issued share capital of COMPASS Pathways plc were reorganized into a single class of ordinary shares through a reverse share split. Accordingly, all of the Company's outstanding shares of COMPASS, including 7,052,003 shares of COMPASS preferred stock were converted into 7,935,663 new ordinary shares of COMPASS Pathways plc. Upon the COMPASS Preferred Stock Conversion, the Company accounted for the transaction under the equity method and recorded the carrying value of the Company's investment in COMPASS' ordinary shares of $53.1 million in equity method investments in the consolidated balance sheets. Concurrently, with the consummation of the COMPASS IPO, all of the Company's investment in COMPASS ordinary shares were converted into American Depository Shares ("ADS"). Accordingly, immediately after the COMPASS IPO, the Company holds 7,935,663 ADS in COMPASS Pathways plc. The COMPASS ADS have identical rights including voting rights as the ordinary shares issued and outstanding.

The carrying value of the investment in COMPASS ordinary shares was reduced to zero at the time of the COMPASS Preferred Stock Conversion due to IPR&D charge with no alternative future use. Since the Company has no obligation to provide financing support to COMPASS, the Company is not required to record further losses exceeding the carrying value of the investment. As of December 31, 2020, the Company owned 26.3% of COMPASS ADS, which includes voting interests through affiliate entities. Based on quoted market prices, the market value of the Company's ownership in COMPASS was $378.1 million as of December 31, 2020.

On May 4, 2021, COMPASS completed an additional round of equity financing through the offering of 4,000,000 ADS. The Company participated in this financing round but did not purchase enough shares to maintain its ownership percentage. The Company acquired 140,000 ADS at an aggregate price of $5.0 million which resulted in a decrease in the Company's equity ownership percentage in COMPASS and a gain on dilution of $16.9 million. Following the acquisition, the Company's ownership of COMPASS ADS was 19.7%. The additional shares purchased was not made to fund prior period losses.

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 ADS at an aggregate purchase price of $47.4 million. The additional shares acquired resulted in an increase in the Company's ownership of COMPASS ADS 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 recently completed its Phase IIb clinical trial. 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. For the year ended December 31, 2021, the Company recognized losses from investments in equity method investees, net of tax of $41.3 million in association with the basis difference charge in the Company's consolidated statements of operations. As of December 31, 2021, the Company owned 22.8% of COMPASS ADS. Based on quoted market prices, the market value of the Company's ownership in COMPASS was $211.4 million as of December 31, 2021.

From the original acquisition of COMPASS common shares in December 2018 through the COMPASS IPO, the Company is deemed to have significant influence over COMPASS through its ownership interest in COMPASS' equity, including the Company's investment in COMPASS preferred stock, and the Company's noncontrolling representation on the COMPASS' board of directors. Accordingly, the Company's investment in COMPASS' common stock was accounted for in accordance with the equity method. The Company's investment in COMPASS' preferred stock did not meet the criteria for in-substance common stock. As such, the investment in COMPASS' preferred stock was accounted for under the measurement alternative as discussed below. Upon the completion of the COMPASS IPO and through December 31, 2021, the Company is deemed to continue to have significant influence over COMPASS primarily through its ownership interest in COMPASS' equity and representation on COMPASS board of directors. Accordingly, the Company's investment in COMPASS' common stock was accounted for in accordance with the equity method through December 31, 2021.

In December 2020, the Company entered into two voting agreements with COMPASS registered shareholders. The voting agreements provided the Company the voting rights attached to the COMPASS ordinary shares held by such COMPASS shareholders. As of December 31, 2020, the Company held 26.3% voting interest in COMPASS, which included the voting rights provided under the voting agreements. The voting agreements did not provide the Company control over COMPASS nor additional board seats and therefore had no impact on the Company's investment in COMPASS under the equity method. In April 2021, both voting agreements were terminated.

During the years ended December 31, 2021 and 2020, the Company recognized its proportionate share of COMPASS' net loss of $10.5 million and $20.6 million, respectively, as losses from investments in equity method investees, net of tax on the consolidated statements of operations. During the year ended December 31, 2020, the Company's proportionate share of COMPASS' net loss was more than the Company's proportionate share using the common stock ownership percentage described above because the aggregate net losses attributable to the Company's investment in COMPASS common stock reduced the carrying amount to zero in the first quarter of 2020.

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, 2021. 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 twelve months ended December 31, 2021, the Company recognized its proportionate share of GABA's net loss of $5.0 million 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. 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, 2021 and December 31, 2020, 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. 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. The contingent obligation to purchase additional shares of Series A preferred stock from GABA was $1.5 million as of December 31, 2021.

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.

The Company has evaluated the contingent obligation (forward) and option and concluded that they both: (i) represent freestanding financial instruments as they are legally detachable and separately exercisable from the underlying shares; and (ii) are equity securities under ASC 321. The Company accounted for the contingent obligation based on the measurement alternative under ASC 321 which is included in Other Investments as of December 31, 2021 and December 31, 2020.

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 twelve months ended December 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, 2021 and December 31, 2020.

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” 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 has less than 20% of ownership interest in DemeRx NB and a noncontrolling representation on the board. The investment in DemeRx NB was recorded in Other Investments on the consolidated balance sheets under the measurement alternative under ASC 321.

In accordance with the DemeRx NB PSPA, the Company also has the option but not the obligation to purchase additional shares of Series A preferred stock at a purchase price of up to $19.0 million with the same price per share as its initial investment. As of December 31, 2021, the Company has not exercised its option to purchase any shares of Series A preferred stock of DemeRx NB. The Company has evaluated the option and concluded that it: (i) represents a freestanding financial instrument as it is legally detachable and separately exercisable from the underlying shares; and (ii) is an equity security under ASC 321. The Company accounted for the option based on the measurement alternative under ASC 321, which is included in Other Investments as of December 31, 2021 and December 31, 2020.

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 for a period of three years from the closing of the initial investment. 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 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. No material research and development services have been performed as of 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. During the year ended December 31, 2021, the Company recognized a mark-to-market ("MTM") loss due to the change in fair value of the investment in IntelGenx's common stock and Warrants of $3.0 million and $9.4 million, respectively, in the consolidated statements of operations, which reduced the carrying amount of the investment to zero.

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, 2021		
	Compass	Neuronasal[1]	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

	December 31, 2020		
	Compass	Neuronasal[1]	GABA
Current assets	$ 202,404	$ 351	$ 3,302
Non-current assets	1,052	10	—
Total assets	$ 203,456	$ 361	$ 3,302
Current liabilities	$ 6,895	$ 686	$ 430
Non-current liabilities	—	48	—
Total liabilities	$ 6,895	$ 734	$ 430

Statements of operations

	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)

	Year Ended December 31, 2020		
	Compass	Neuronasal[1]	GABA
Revenue	$ —	$ —	$ —
Loss from continuing operations	$ (51,393)	$ (1,208)	$ (2,685)
Net loss	$ (60,334)	$ (1,208)	$ (2,685)

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

6. Notes Receivable

Short Term Notes Receivable—Related Party

Investment in COMPASS Convertible Promissory Note-Related Party

On September 27, 2019, the Company purchased a convertible promissory note for a total principal amount of £3.0 million or $4.0 million. On November 6, 2019, the Company purchased an additional convertible promissory note for £3.2 million or $4.2 million (the "COMPASS Notes"). The COMPASS Notes bear interest at an annual rate of 3% and are due one year after the date of the note. The Company will earn interest on the COMPASS Notes only if a conversion event does not occur. The Conversion event is a new qualifying financing round; the Company has no control of the conversion event. At the time of issuance, the Company determined it was probable that the contingent event would occur and therefore, did not record interest income for either COMPASS convertible promissory note as of the date of conversion on April 17, 2020.

The COMPASS Notes are automatically convertible into shares of the class of equity securities issued upon the occurrence of a qualified equity financing in which COMPASS receives at least £25 million or $33.2 million, or if a noteholder majority has approved a non-qualifying equity financing in which COMPASS receives £25 million or $33.2 million, or less. On the conversion date, COMPASS shall convert the principal amount of the COMPASS Notes into a number of new fully paid preferred shares at a price per share representing a 15% discount to the price per share paid for preferred shares by the investors in a qualified equity financing or approved non-qualifying equity financing the conversion price is subject to a maximum price per share of £2,397 or $3,181.

The Company is eligible to elect the fair value option under and bypass analysis of the potential embedded derivative features described above and further analysis of bifurcation of any such derivatives and has elected such option. The Company believes that the fair value option better reflects the underlying economics of the COMPASS Notes. As a result, the COMPASS Notes were recorded at its fair value upon issuance and will be subsequently remeasured at each reporting date until settled or converted. Changes in the fair value of the COMPASS Notes will continue to be recognized until the notes are converted or repaid. Under the fair value election, changes in fair value will be reported in the consolidated statements of operations as change in fair value of short term notes receivable—related party. The Company initially recorded the notes at £6.2 million or $7.8 million since fair value approximated the purchase price of the COMPASS Notes.

On April 17, 2020, in a transaction that constituted a qualified financing round, COMPASS issued and sold shares of Series B preferred stock to other investors resulting in proceeds of approximately $49.8 million. In connection with the qualified financing, all of the Company's outstanding aggregate principal under the COMPASS Notes totaling £6.2 million or $7.6 million was converted into shares of COMPASS Series B preferred stock. The COMPASS Notes was converted at a price equal to 85% of the Series B issuance price paid by the investors in COMPASS' Series B qualified financing as per the terms of the promissory notes. Under the fair value option, the notes were remeasured to fair value to $9.0 million immediately prior to conversion. Once the notes were converted, the acquired shares were recorded at a price per share equal to the fair value of the Series B shares of £1,350 or $1,654. The change in fair value in the COMPASS Notes from December 31, 2019 to its conversion to Series B preferred stock in April 2020, were $0.7 million and included in change in fair value of short term notes receivable—related party in the consolidated statements of operations. See Note 5 for further information regarding the Company's equity method investment in COMPASS.

Loan to a Compass Shareholder

On December 3, 2020, the Company entered into loan and voting agreements with a COMPASS shareholder (collectively, the "Compass Shareholder Agreement") for £0.7 million or approximately $0.9 million. The purpose of the Compass Shareholder Agreement is to allow the COMPASS shareholder to exercise his stock options in COMPASS Pathways plc and to transfer the relevant rights (i.e. voting rights) attached to the ordinary shares to the Company. The Company has the full power to exercise these relevant rights at its absolute discretion in its own best interest. These relevant rights are valid until the COMPASS shareholder no longer holds the ordinary shares of COMPASS Pathways plc. This loan bears no interest and shall be repayable on or before April 1, 2022. Pursuant to the Compass Shareholder Agreement, the COMPASS shareholder shall not transfer, assign or otherwise dispose of any of the shares without the prior written consent of the Company.

The Company recorded the Compass Shareholder Agreement at cost as a short term note receivable which included a principal balance of the note, net of any payments received, on its consolidated balance sheets. As of December 31, 2020, the Compass Shareholder Agreement has an outstanding balance of $0.9 million. In April 2021, the Compass Shareholder Agreement was terminated.

Long Term Notes Receivable – related party

Loan to IntelGenx Corp.

On March 8, 2021, the Company and IntelGenx entered into a loan agreement under which the Company provided the 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 additional investment in IntelGenx Tech Corp. by the Company. On May 14, 2021, the Company amended the Term Loans 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 amended the Term Loans, and 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 will 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, net of any payments received, in Long term notes receivables – related parties on its consolidated balance sheets. As of December 31, 2021, the Term Loans have an outstanding balance of $2.5 million. During the year ended December 31, 2021, the recognized interest income associated with the Term Loans was immaterial.

Investment in DemeRx Promissory Note—Related Party

On January 3, 2020, DemeRx IB loaned to DemeRx $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"). The DemeRx Note bears interest on the unpaid principal balance of the note at a 6% rate per annum, computed on the basis of a 360-day year, from until payment in full of all outstanding balance of the DemeRx Note. Such interest shall be accrued and be payable upon the earlier of the DemeRx Maturity Date or acceleration as a result of an event of default. 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 the sole discretion pay any amount due under this note, in cash or through cancellation shares of common stock of DemeRx IB, par value $0.0001 per share, of the fair market value of such shares. In addition, DemeRx has the right to prepay the principal amount in whole or in part upon three (3) days' written notice to DemeRx IB without payment of any premium or penalty, and any such prepayment shall be applied to reduce the principal payment of the DemeRx Note. The Company concluded that these embedded features do not meet the criteria to be bifurcated and separately accounted for as derivatives. Upon the occurrence of an event of default, DemeRx IB can declare the principal and any accrued and unpaid interests of the DemeRx Note to be immediately due and payable and during the occurrence and continuance of any event of default, the interest rate will increase to a default rate of 11% from 6% from the date of such event of default until the earlier of (i) the waiver of such event of default by DemeRx IB, or (ii) the payment in full of all outstanding balance of the DemeRx Note. The Company concluded that this feature met the definition of a derivative which required bifurcation. As the probability of this event of default occurring was less than remote, the Company concluded that the fair value of the embedded derivative ascribed to this feature were de minimis.

The Company recorded the DemeRx Note at cost which included the principal balance of the note and accrued interest, net of any payments received, on its consolidated balance sheets. As of December 31, 2021 and 2020, the DemeRx Note had an outstanding balance of $1.1 million. For the years ended December 31, 2021 and 2020, 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.

7. Fair Value Measurement

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

	Fair Value Measurements as of December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 271,856	$ —	$ —	$ 271,856
Other investment held 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

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				$ —
Liabilities:				
Contingent consideration liability - related parties	$ —	$ —	$ 1,705	$ 1,705
Derivative liability	—	—	214	214
	$ —	$ —	$ 1,919	$ 1,919

During the years ended December 31, 2021 and 2020, there were no transfers between Level 1, Level 2 or Level 3.

Valuation of COMPASS Note Receivable-Related Party

The fair value of the COMPASS Notes at issuance and subsequent financial reporting dates was estimated based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The Company estimated the fair value of the COMPASS Notes during the first quarter of 2020 and immediately prior to the conversion of the notes in April 2020 using the fair value of the Series B preferred stock of COMPASS. The fair value of the Notes was estimated to be $9.0 million immediately prior to the conversion of the notes. Once the notes were converted, the acquired shares were recorded at a price per share equal to the fair value of the Series B shares of £1,350 or $1,654. The change in fair value in the COMPASS Notes from December 31, 2019 to its conversion to Series B preferred stock in April 2020, were $0.7 million and included in change in fair value of short term notes receivable—related party in the consolidated statements of operations for the year ended December 31, 2020.

Contingent Consideration Liability—Related Parties—Perception, Innaris Bio, 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, 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 as of December 31, 2021.

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. As of the fourth quarter of 2020, Perception negotiated a license transaction with a third-party pharmaceutical company that closed in March 2021. The Company used a scenario-based model ("SBM") to consider the Company's estimate of 80 percent probability that the transaction would happen and the 20 percent probability that it would fail to close. The valuation used inputs that were unobservable inputs with the most significant being the discount rates for royalties on projected commercial revenue and clinical milestones, probability of the transaction closing, and probability of success estimates over the following ten years.

As of December 31, 2021, the license transaction had closed and the scenario-based method was no longer used (See Note 16). The valuation used inputs that were unobservable with the most significant being the discount rates for royalties on projected clinical milestones and commercial revenue and the probability of success estimates over the following ten years.

The fair value of the contingent milestone and royalty liabilities for Perception was estimated to be $1.5 million and $1.7 million as of December 31, 2021 and December 31, 2020, respectively.

The fair value of the contingent milestone and royalty liabilities could change in future periods depending on the prospects for the first patient dosing and the outcome of obtaining approval from FDA or regulatory authorities for potential drug product using the solgel-based direct-to-brain intranasal drug delivery technology, and whether the Company realizes a significant increase or decrease in sales upon commercialization. The most significant assumptions in the income approach valuation technique used to estimate the contingent liabilities are the probability of each milestone being met, the probability of number of drug products being developed, projected milestone timing and discount rate.

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

		December 31, 2021		December 31, 2020	
Valuation Technique	Significant Unobservable Inputs	Input Range	Weighted Average	Input Range	Weighted Average
Discounted cash flow	Milestone contingent consideration:				
	Discount rate	11.4%	11.4%	8.4% to 14.1%	9.4%
	Probability of the milestone	51.9%	51.9%	10.5% to 48.7%	34.8%
Discounted cash flow with SBM	Royalty contingent consideration:				
	Discount rate for royalties	19.2% - 20.1%	19.9%	12.0% to 13.0%	12.5%
	Discount rate for royalties on milestones	10.9% - 11.8%	11.6%	8.4%	8.4%
	Probability of success rate	26.5% to 100.0%	35.6%	3.95% to 100.0%	12.6%
	Probability of the close of the license transaction [(1)]	N/A	N/A	80.0%	80.0%

(1) This input was used in fourth quarter of 2020 in relation to a potential license transaction that Perception had with a third-party pharmaceutical company.

The fair value of the contingent liability for TryptageniX was estimated to be $0.9 million as of December 31, 2021. 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. The Company determined that the change in fair value from the acquisition date of December 3, 2021 to December 31, 2021 was not material.

Valuation of 2020 Convertible Notes Payable

The fair value of the 2020 Convertible Notes at issuance and at each reporting period was estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company used a SBM to incorporate estimates and assumptions concerning company prospects and market indications into a model to estimate the value of the notes. The most significant estimates and assumptions used as inputs in the SBM valuation technique impacting the fair value of the 2020 Convertible Notes are those concerning type, timing and probability of specific scenario outcomes. At the issuance dates of the 2020 Convertible Notes, a qualified financing was assumed to occur within the year following issuance. Specifically, the Company discounted the cash flows for fixed payments by using annualized discount rates that were applied across valuation dates from issuance dates of the 2020 Convertible Notes until conversion in November 2020. The discount rates were based on certain considerations including: time to payment, an assessment of the credit position of atai, market yields of companies with similar credit risk at the date of valuation estimation, and calibrated rates based on the fair value relative to the original issue price from the 2020 Convertible Notes.

Payments that are sensitive to the total equity value of the Company at the date of payment were valued at each valuation date using an option pricing model ("OPM"). Key assumptions used in the OPM included risk free rate, volatility across the period of the valuation dates, dividend yield, and a period of estimation commensurate with time until payment. The inputs to the option pricing model were determined based on assessment of the Company's most recent financing transaction, assessed and adjusted for the market value of a group of publicly traded peer guideline companies and relevant equity indices as of each valuation date from issuance to conversion.

The following table summarizes significant unobservable inputs by valuation technique that are included in the valuation of the 2020 Convertible Notes from the issuance date of the notes in January 2020 to the note conversion date in November 2020:

Valuation Technique	Significant Unobservable Inputs	Input Range	Weighted Average
SBM	Discount rate	-0.5% to 7.2%	0.8%
	Probability scenarios:		
	Conversion upon a financing event	50% to 90%	65.5%
OPM	Volatility	70.0% to 85.0%	79.0%
	Dividend yield	0%	0%

Valuation of Derivative Liability—Perception Convertible Notes

The derivative liability in the table above relates to the embedded conversion features in connection with the Perception Convertible Notes issued in 2020 and 2021 discussed in Note 10. The Perception March 2020 Notes contained a derivative, which is related to embedded conversion feature upon a qualified financing transaction. The Perception December 2020 Notes contained a derivative, which is related to embedded conversion features upon a qualified financing transaction and a licensing transaction. The fair value of the embedded conversion features at issuance of the Perception Convertible Notes and subsequent financial reporting dates was estimated based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The Company used a SBM to incorporate estimates and assumptions concerning company prospects and market indications into a model to estimate the value of the derivative liability. An SBM considers a range of various potential scenario outcomes assumed to occur with associated probabilities. Cash flow outcomes are then discounted to present value to estimate fair value. The SBM procedure is as follows: (i) estimate future cash flows that arise from scenario outcomes, (ii) discount the cash flows to present value using a market-based discount rate and (iii) probability weight the present values to form a probability weighted, expected return analysis that estimates fair value at the subject valuation date. The most significant estimates and assumptions used as inputs in the SBM valuation technique impacting the fair value of the embedded conversion features are those concerning the scenario outcomes' type, timing and probability.

At the issuance dates of the Perception Convertible Notes and at December 31, 2020, a qualified financing and a licensing transaction were assumed to occur within the year following issuance which the Company estimated 20 percent and 80 percent probability of occurrence of a qualified financing and a licensing transaction, respectively.

As the derivative liability associated with the Perception March 2020 Notes was related to the embedded conversion feature upon a qualified financing transaction the fair value of the derivative liability associated with the Perception March 2020 Notes was reduced to zero because of a zero percent probability of the occurrence of a qualified financing transaction as of December 31, 2021.

The Company calculated the payment due to the holders of Perception Convertible Notes with and without the embedded conversion feature and discounted to present value. The Company discounted the cash flows using a discount rate of 17.0 percent annualized at the

issuance dates, and at December 31, 2020 based on an assessment of the credit position of Perception and market yields of companies with similar credit risk at the date of valuation estimation.

On May 31, 2021, the Company issued convertible notes under the Second Tranche Funding (see Note 10). In connection with the issuance of these notes, the Company determined the fair value of the derivative liability related to the embedded conversion option by calculating the payment due to the holders of these notes with and without the conversion feature. The Company discounted the cash flows using a discount rate of 18.0 percent annualized at the issuance date, based on an assessment of the credit position of Perception and market yields of companies with similar credit risk at the date of valuation estimation.

On June 10, 2021, the Perception Convertible Notes converted into shares of Series A preferred stock of Perception pursuant to their original terms. The Company remeasured the embedded derivatives related to the Perception Convertible Notes at fair value immediately prior to conversion on June 10, 2021. The Company calculated the payments due to the holders of Perception Convertible Notes with and without the conversion feature. The Company discounted the cash flows using a discount rate of 18.0 percent at June 10, 2021, based on an assessment of the credit position of Perception and market yields of companies with similar credit risk at the date of valuation estimation.

The fair value of the embedded conversion features, including the embedded conversion features associated with the notes issued under the Second Tranche Funding was determined to be $0.8 million immediately before the conversion of the Perception Convertible Notes on June 10, 2021 and reduced to zero upon conversion of the notes. The fair value of the embedded conversion features was determined to be $0.2 million as of December 31, 2020.

The significant unobservable inputs that are included in the valuation of the derivative liability as of December 31, 2020 include:

	December 31, 2020	
Significant Unobservable Inputs	**Input Range**	**Weighted Average**
Discount rate	17.0%	17.0%
Expected term	1 year	1 year
Probability scenarios:		
Qualified financing transaction	20%	20%
Licensing transaction	80%	80%

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%

IntelGenx Common Stock, Initial Warrants and Additional Units Warrant

The Company's investment in IntelGenx consists of Common Shares, Initial Warrants and Additional Units Warrant (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 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 13.7% as of May 14, 2021 and 5.0% as of December 31, 2021. The Company estimated a DLOM in connection with the valuation of the Common Shares at initial recognition and as of December 31, 2021 to reflect the restrictions associated with the Common Shares. As of December 31, 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 written down to zero as of December 31, 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 written down to zero as of December 31, 2021.

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

	December 31, 2021
Value of Underlying	$ 0.34
Expected Volatility	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 (GBM) 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 written down to zero as of December 31, 2021.

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

	December 31, 2021
Stock Price	$ 0.34
Expected Volatility	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):

	Compass Notes Receivable - related party	2020 Convertible Notes Payable	Other Investments Held at Fair Value	Contingent Consideration Liability - Related Parties	Derivative Liability	Warrant Liability
Balance as of December 31, 2019	$ 8,244	$ —	$ —	$ 572	$ —	$ —
Initial fair value of instrument	—	—	—	—	364	—
Issuance of notes payable	—	30,437	—	—	—	—
Conversion of notes receivable	(9,003)	—	—	—	—	—
Conversion of notes payable	—	(50,059)	—	—	—	—
Change in fair value	718	16,974	—	1,133	(150)	—
Foreign currency transaction adjustments	41	2,648	—	—	—	—
Balance as of December 31, 2020	$ —	$ —	$ —	$ 1,705	$ 214	$ —
Initial fair value of instrument	—	—	9,359	951	647	249
Change in fair value	—	—	(9,359)	(173)	(41)	87
Extinguishment of liability	—	—	—	—	(820)	—
Balance as of December 31, 2021	$ —	$ —	$ —	$ 2,483	$ —	$ 336

8. Prepaid Expenses and Other Current Assets

Prepaid expenses consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Prepaid research and development related expenses	$ 2,692	$ 313
Research and development tax credit	742	556
Sales tax receivables	4,664	509
Prepaid insurance	3,049	144
Other	756	554
Total	$ 11,903	$ 2,076

9. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Accrued accounting, legal, and other professional fees	$ 2,667	$ 2,858
Taxes payable	8,137	997
Accrued external research and development expenses	861	347
Accrued payroll	2,832	1,098
Accrued advisory fees	169	3,819
Other liabilities	163	96
Total	$ 14,829	$ 9,215

10. 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, 2021	December 31, 2020
Convertible notes issued in November 2018	$ 125	$ 195
Convertible notes issued in October 2020	623	1,022
Unamortized discount and deferred issuance costs	(5)	(18)
Total	$ 743	$ 1,199

During November 2018, the Company executed a terms and conditions agreement (the "Convertible Note Agreement") under which it would issue up to €1.0 million or $1.2 million in 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, certain investors subscribed to the Convertible Note Agreement and the Company issued convertible promissory notes in the aggregate principal amount of €0.2 million or $0.2 million.

In October 2020, certain investors subscribed to the Convertible Note Agreement and the Company issued the remainder of the 2018 Convertible Notes in the aggregate principal amount of €0.8 million or $1.0 million (collectively, the "2018 Convertible Notes"). The total aggregate principal amount of the 2018 Convertible Notes is $1.2 million as of December 31, 2020. 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.

In connection with the Convertible Note Agreement, the Company issued convertible notes in the principal amounts of €0.1 million or $0.1 million to the founders of Perception, who are also related parties of the Company in November 2018 (See Note 17). Perception is a biotech

firm acquired by the Company on November 5, 2018. Upon the purchase of certain assets of Perception in November 2018, Perception was deemed to have been a VIE, of which the Company is the primary beneficiary (See Note 4).

In addition, in connection with the Convertible Note Agreement, the Company issued convertible notes in the principal amounts of €0.5 million or $0.6 million to Apeiron, the family office of the Company's founder, and €0.3 million or $0.4 million to one other shareholder of the Company and the founder of COMPASS in October 2020.

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.

Volatility	74.0%
Time until maturity	4.96 - 4.97 years
Dividend yield	0%
Risk-free interest rate	(0.63)% - (0.76)%
Conversion payment	€17
Fair value of ordinary shares	€75

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 in ATAI Life Sciences AG to ATAI Life Sciences N.V. and received sixteen shares in ATAI Life Sciences N.V. for one share in ATAI Life Sciences AG. In September and October 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 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. 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.

2020 Convertible Promissory Notes

In January 2020, the Company executed a terms and conditions agreement (the "2020 Convertible Note Agreement") under which it would issue up to €30.0 million, or $33.5 million, in convertible promissory notes to various investors. The total aggregate principal amount of the remaining outstanding 2020 Convertible Notes was $32.2 million as of November 2020. The 2020 Convertible Notes converted into 8,773,056 of shares of the Company's common stock in November 2020.

For the twelve months ended December 31, 2020, the interest expense and change in fair value in the 2020 Convertible Notes from its various issuance dates to the conversion date totaled $17.0 million and is included in change in fair value of convertible promissory notes in the consolidated statements of operations.

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 are 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 are 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 during the twelve months ended December 31, 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 twelve months 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 twelve months ended December 31, 2021. As of December 31, 2020, the unamortized debt discount on the Perception Convertible Notes was $0.3 million. 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.

Line of Credit Agreements

In June 2020, the Company entered into a €4.0 million or approximately $4.5 million credit line agreement with Attersee. In September 2020, the Company entered into an amendment to the Attersee credit line agreement, pursuant to which the Company decreased the credit line to €2.0 million or approximately $2.4 million. This credit line bears an annual borrowing rate of 2.5% and an annual facility fee of 0.75%, and has a final maturity of April 30, 2023. As of December 31, 2020, there were no outstanding borrowings under this credit line agreement. In July 2021, the Company terminated its credit line with Attersee, which remained unused as of the date of cancellation.

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, 2021 and December 31, 2020, 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, 2021, 0 shares were 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 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 our shareholders approved the 2021 Incentive Award Plan ("2021 Incentive Plan"). The 2021 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 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 38,704,944 shares of common stock, for issuance to executive officers, directors and employees and consultants of the Company pursuant to the 2021 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, 2021, 34,026,163 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 five-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 December 31, 2020 stock options outstanding balance noted below includes 3,176,976 stock options that will vest over a four-year service period, only if and when a "Liquidity Event" (as defined in the 2020 Incentive Plan) occurs within five years of the date of grant. During the year ended December 31, 2021, the Company modified the vesting terms of 2,464,720 of these options held by 12 employees such that, if the Company achieves an Initial Public Offering (as defined in the awards) by June 30, 2021 or December 31, 2021, an additional 25% or 12.5%, respectively, will accelerate and vest upon the occurrence of the transaction. In each case provided, however, no option shall become vested before the first anniversary of the respective vesting start date. The Company applied modification accounting under ASC 718, which resulted in a new measurement of compensation cost, and the original grant-date fair value of the award is no longer used to measure compensation cost for the award. The weighted average fair value on the new measurement date amounted to $4.97.

In addition, during the year ended December 31, 2021, the Company cancelled 1,152,192 stock options held by 3 employees and concurrently granted 4,543,936 HSOP Options under the HSOP Plan (as defined and described below) ("Exchange Options"). The Company applied modification accounting under ASC 718, which resulted in a new measurement of compensation cost, and the original grant-date fair value of the award is no longer used to measure compensation cost for the award. The weighted average fair value on the new measurement date amounted to $4.20. Refer to the ATAI Life Sciences Hurdle Share Option Plan for more information on these stock options.

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, 2020 to December 31, 2021:

	Number of Options		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	11,331,232		$ 1.54	4.64	$ 47,735
Granted	17,990,952	(1)	9.69	—	—
Exercised	(379,049)		2.44	—	—
Cancelled or forfeited	(2,255,515)	(2)	3.52	—	—
Outstanding as of December 31, 2021	26,687,620	(3)	$ 6.85	4.85	$ 74,525
Options exercisable as of December 31, 2021	6,468,770		$ 1.21	3.63	$ 41,500

(1) Includes (a) 5,391,184 stock options that will vest over a two to four-year service period, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant. If the Company achieves an IPO (as defined in the awards) by June 30, 2021 or December 31, 2021, an additional 25% or 12.5%, respectively, the stock options will accelerate and vest upon the occurrence of the transaction, (b) 5,241,785 stock options that will vest over a one to four-year service period, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant (c) 1,460,784 stock options that will vest over a three to four-year service period and upon the satisfaction of specified performance-based vesting conditions, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (d) 624,000 stock options that will vest over a three-year service period, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (e) 400,688 stock options that will vest over a four-year service period and upon the satisfaction of specified performance-based vesting conditions including liquidity-based conditions, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant. If the Company achieves an IPO (as defined in the awards) by June 30, 2021 or December 31, 2021, an additional 25% or 12.5%, respectively, will accelerate and satisfy the service-based vesting condition upon the occurrence of the transaction, (f) 400,000 stock options that will 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, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (g) 338,112 stock options that will vest over a four-year service period and upon the satisfaction of specified performance-based vesting conditions including liquidity-based conditions, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (h) 100,640 stock options that will vest over a four-year service period and upon the satisfaction of specified performance-based vesting conditions, only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (i) 94,096 stock options that will vest only if and when a "Liquidity Event" (as defined in the awards) occurs within five years of the date of grant, (j) 3,919,997 stock options that will vest over a three to four-year service period, and (l) 19,666 stock options that were 100% vested upon grant.

(2) Includes 1,152,192 Exchange Options

(3) With the satisfaction of the Liquidity Event in June 2021, the 20,218,850 outstanding unvested stock options includes (a) 15,240,355 that will continue to vest over a one to four-year service period, (b) 4,778,495 that will continue to vest over a three to four-year service period and upon the satisfaction of specified performance-based vesting conditions, and (c) 200,000 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.

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. During the twelve months ended December 31, 2021, the assumptions used in the Black-Scholes option pricing model were as follows:

	Year Ended December 31,	
	2021	2020
Weighted average expected term in years	4.16	3.92
Weighted average expected stock price volatility	80.0%	71.1%
Risk-free interest rate	(0.76)%-1.33%	0.20% - 0.22%
Expected dividend yield	0%	0%

For the twelve months ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense of $41.3 million and $5.4 million, respectively.

As of December 31, 2021, total unrecognized compensation cost related to the unvested stock-based awards was $95.8 million, which is expected to be recognized over a weighted average period of 2.16 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, 2021, 132,752 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, 2021, 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 for from December 31, 2020 to December 31, 2021:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	—	—	—	—
Granted	7,281,376 (1)	6.64	—	—
Exercised	(102,128)	6.60	—	—
Cancelled or forfeited	(132,752)	6.64	—	—
Outstanding as of December 31, 2021	7,046,496	$ 6.64	14.01	$ 6,961
Options exercisable as of December 31, 2021	3,936,475	$ 6.64	14.01	$ 3,901

(1) Includes 4,543,936 Exchange Options

The weighted-average grant-date fair value of options granted during the twelve months ended December 31, 2021, was $4.37.

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. During the twelve months ended December 31, 2021, the assumptions used in the Black-Scholes option pricing model were as follows:

	December 31, 2021
Weighted average expected term in years	8.0
Weighted average expected stock price volatility	70.0%
Risk-free interest rate	(0.70)%-(0.65)%
Expected dividend yield	0%

For the twelve months ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense of $21.1 million and $0.0 million, respectively.

As of December 31, 2021, total unrecognized compensation cost related to the unvested stock-based awards was $8.8 million which is expected to be recognized over a weighted average period of 1.18 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, 2021 and 2020, the Company recorded share-based compensation expense of $0.9 million and $0.3 million, respectively, in relation to subsidiary EIPs. As of December 31, 2021, there was $1.2 million of total unrecognized stock-based compensation expense related to unvested EIP awards to employees and non-employee directors expected to be recognized over a weighted-average period of approximately 1.75 years. As of December 31, 2021, 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 $0.4 million, which will be recognized only upon the satisfaction of the vesting conditions.

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, 2021, which includes expense related to stock options and restricted stock awards (in thousands):

	Twelve Months 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

The following table summarizes the total stock-based compensation expense by function for the twelve months ended December 31, 2020, which includes expense related to stock options and restricted stock awards (in thousands):

	Twelve Months Ended December 31, 2020			
	Atai ESOP	Atai HSOP	Other Subsidiaries Equity Plan	Total
Research and development	$ —	$ —	$ 271	$ 271
General and administrative	66,874	—	13	$ 66,887
Total share based compensation expense	$ 66,874	$ —	$ 284	$ 67,158

In connection with the convertible notes – related parties issued in October 2020 (See Note 10), the Company recorded stock-based compensation expense for the year ended December 31, 2020 of $61.5 million which is included in general and administrative expense on the consolidated statements of operations and in the table above and is recorded within additional paid in capital within equity.

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,	
	2021	2020
Germany	$ (89,061)	$ (75,966)
International	(47,540)	(25,847)
Total loss before income taxes and loss from equity method investments	$ (136,601)	$ (101,813)

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

	Year Ended December 31,	
	2021	2020
Current income tax provision (benefit):		
Germany	$ —	$ —
International	1,117	305
Total current income tax provision:	$ 1,117	$ 305
Deferred income tax provision (benefit):		
Germany	$ —	$ —
International	(5,106)	—
Total deferred income tax provision:	(5,106)	—
Total income tax provision:	$ (3,989)	$ 305

The international current tax provision for December 31, 2021 and 2020 is primarily comprised of corporate income taxes incurred in the United States and the United Kingdom.

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,	
	2021	2020
Loss before income taxes:		
Germany	$ (89,061)	$ (75,966)
International	(47,540)	(25,847)
Total loss before income taxes:	(136,601)	(101,813)
German statutory rate	30.18%	30.18%
Expected income tax expense (benefit)	(41,220)	(30,722)
US state income taxes, net of US federal tax benefit and valuation allowance	$ 132	$ 74
International tax rate differential	4,222	2,304
Fair value adjustments	—	(247)
IPR&D charges and acquisition adjustments	3,251	2,164
Effect of R&D credit incentives	(3)	240
Fair value adjustments	2,934	(6,175)
Effect of statutory to US GAAP accounting adjustments	(10,409)	
Compensation Expenses not deductible under IRC Section 162(m)	1,690	
Expenses not deductible for tax purposes	612	(55)
Effect of German participation exemption on outside basis differences	—	(5)
Effect of non-deductible compensation in respect of convertible notes	—	18,558
Effect of conversion of convertible notes	—	4,846
Effect of share-based compensation expense	192	—
Other	(657)	(1)
Change in German and International valuation allowance	35,267	9,324
Total income tax expense	$ (3,989)	$ 305
Effective income tax rate:	2.92%	(0.30)%

The Company is headquartered in Berlin, Germany and has subsidiaries in the United States, Australia, and the United Kingdom 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 two of its United States subsidiaries and its United Kingdom subsidiary. The weighted-average combined German corporate income tax rate for the year ended December 31, 2020 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, 2020 and 2021 was 21.00%. The weighted-average Australia corporate income tax rate for the year ended December 31, 2020 and 2021 was 27.50%. The weighted-average United Kingdom corporate income tax rate for the year ended December 31, 2021 was 19.00%.

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

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

	Year Ended December 31,	
	2021	2020
Deferred tax assets:		
German tax loss carryforward	$ 31,149	$ 5,956
International tax loss carryforward	8,618	6,321
Intangible assets	66	57
Share compensation	17,231	1,698
Other deductible timing differences	829	194
Total deferred tax assets, gross	57,893	14,226
Valuation allowance	(49,442)	(14,174)
Total deferred tax assets, net	$ 8,451	$ 52
Deferred tax liabilities:		
Other taxable timing differences	$ (17)	$ (51)
Unrealized foreign exchange	$ (3,326)	$ —
Outside basis differences in equity and other investments	(2)	(1)
Total deferred tax liabilities	(3,345)	(52)
Total deferred tax asset (liability)	$ 5,106	$ —

The valuation allowance provided against net deferred tax assets as of December 31, 2020 and 2021 was $14.2 million and $49.4 million, respectively. The valuation allowance recorded at both periods was primarily related to German and international tax loss carryforwards and stock-based compensation timing differences that, in the judgement of management, are not more-likely-than-not, to be realized. Net deferred tax assets are recognized with regard to certain subsidiaries in the United States and United Kingdom, which generate taxable profits.

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. We recognize net deferred tax assets with regard to two subsidiaries in the United States and the United Kingdom for which sufficient positive evidence exists, including current and projected future taxable income, that we believe it is more-likely-than-not that such 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 Internal Revenue Code ("IRC"). Management considers the Company's limited history and historical tax losses, future projected taxable income, including the character and jurisdiction of such income, the scheduled reversal of deferred tax liabilities (including the effect in available carryback and carryforward periods), and tax-planning strategies in making this assessment. In the event that there is a change in the ability to recover deferred tax assets, our income tax provision would increase or decrease in the period in which the assessment is changed.

We note that a Section 382 analysis was undertaken in 2021, which determined that the tax loss carryforwards recorded by one United States subsidiary were able to be utilized in full, offsetting the entity's United States taxable income generated for the year ended December 31, 2021, subject to statutory limitations.

The Company has limited prior earnings history and, due to the early stages of its development and research activities, is expected to generate losses for the next several years in certain jurisdictions 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, 2021 and 2020, the Company does not have any significant unremitted earnings in its international subsidiaries.

The Company's gross tax loss carryforward for tax return purposes are as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Germany tax losses	$ 103,232	$ 19,738
International tax losses	31,875	21,425
Total	$ 135,107	$ 41,163

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 2020 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, 2020 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):

	Year Ended December 31,	
	2021	2020
Numerator:		
Net loss	$ (174,244)	$ (178,625)
Net income (loss) attributable to redeemable noncontrolling interests and noncontrolling interests	(6,436)	(8,782)
Net income attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (167,808)	$ (169,843)
Denominator:		
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. Stockholders - basic and diluted	138,265,859	93,019,072
Net income per share attributable to ATAI Life Sciences N.V. shareholders - basic and diluted	$ (1.21)	$ (1.83)

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 maximum amount of outstanding shares of potentially dilutive securities that were excluded from the computation of diluted net income (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,	
	2021	2020
Options to purchase common stock	26,687,820	11,331,232
HSOP options to purchase common stock	7,179,248	—
2018 Convertible Promissory Notes - Related Parties (Note 11)	10,521,824	16,000,000
	44,388,892	27,331,232

In September and October 2021, several investors elected to convert their 2018 Convertible Notes into shares of ATAI Life Sciences N.V. The remaining 2018 Convertible Notes would be issuable upon the exercise of conversion rights of convertible note holders for 657,614 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.

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, the Company entered into a license and collaboration agreement (the "Otsuka Agreement") with Otsuka under which the Company 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. The Company retained all rights to PCN-101 outside of Japan.

Otsuka owed the Company an upfront, non-refundable payment of $20.0 million as of the execution of the Otsuka Agreement. The Company 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 the Company a tiered, double-digit royalties 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 twelve months ended December 31, 2021, there have been no additional milestones achieved under the Otsuka Agreement, except for the upfront transfer of the license. The Company 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 during the twelve months ended December 31, 2021. Additionally, the Company recognized revenues of $0.6 million related to certain research and development services during the twelve months ended December 31, 2021. As of December 31, 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, 2021 and 2020, 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 period from November 2020 (date of acquisition) to December 31, 2020, 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 with 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% of Kures common stock on a fully diluted basis, in accordance with the terms and conditions of the SPA. Kures shall, from time to time, 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. The antidilution protection provision shall be maintained up to and through the achievement of certain milestone events. At the acquisition date, the Company recorded the fair value of the shares of Kures common stock issued to Columbia of $0.1 million to atai's additional-paid-in-capital and a debit to research and development expense for the corresponding acquired in-process research and development as it had no alternative future use at the time of the acquisition. In addition, Kures is obligated to pay tiered royalties ranging in the low to mid-single-digit percentage based on net sales of products licensed under the agreement. If Kures receives revenue from sublicensing any of its rights under the agreement, Kures is also obligated to pay a portion of that revenue to Columbia. Starting from the fourth anniversary of the effective date of the Kures License Agreement, Kures is obligated to pay Columbia annual license fees ranging from $10,000 to $0.1 million, creditable against royalties. Kures is also obligated to make milestone payments aggregating up to $15.5 million upon the achievement of certain clinical or regulatory and sales-based milestones for the first indication for each of the licensed product and up to $7.3 million for each subsequent indication for each of such products. In addition, Kures is obligated to pay Columbia a portion of the non-royalty sublicense payments it receives from a third party receiving a sublicense to practice the rights licensed to Kures under the license agreement, ranging from a low teen to low double-digit percentage. Kures has the right to terminate the Columbia agreement for any reason upon a 90-day notice and if Columbia materially breaches the agreement and fails to remedy any such default. Columbia has the right to terminate the Columbia agreement if Kures 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 Columbia's rights to any milestone payments, royalties, and other payments described above. The Columbia agreement will remain in effect until terminated by the parties according to their rights. During the twelve months ended December 31, 2021, Kures paid $0.2 million to Columbia in connection with the Kures License Agreement. During the years ended December 31, 2021 and 2020, respectively, the Company made no material payments pursuant to 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. 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. During the year ended December 31 2021, the Company 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 atai, 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. atai has the right, but not the obligation, to settle future royalty payments based on net product sales with the Company's common stock. atai and Dalriada will determine the equity settlement based on a price per share determined by both parties.

In January 2022, in accordance with the Invyxis ESLA, Invyxis paid an upfront deposit of $1.1 million, which was capitalized as prepaid research and development expense. The Company will expense the upfront deposit as the services are performed as a component of

research and development expense in the consolidated statements of operations. During the twelve months ended December 31, 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 18.0% and 21.7% of the outstanding common stock in the Company as of December 31, 2021 and December 31, 2020, respectively. Galaxy is a NYC-based multi-strategy investment firm that owns 6.7% and 8% of the outstanding common stock in the Company as of December 31, 2021 and December 31, 2020, respectively. HCS is a German venture capital firm that owns 3.6% and 6% of the outstanding common stock in the Company as of December 31, 2021 and December 31, 2020, 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

In November and December 2020, in connection with the Company's issuance of 14,933,344 shares of common stock of €0.10 par value, at a price of €4.69 or $5.56 per share, the Company issued common shares to Apeiron for a total purchase price of $11.9 million, and issued common shares to Galaxy for a total purchase price of $4.7 million (See Note 11).

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. During 2019, the Company engaged Koch to provide banking, advisory, other services. In addition, Apeiron has existing advisory agreements separately with SMC and Koch. Pursuant to the advisory agreements, SMC and Koch will pay a certain portion of advisory fees received from the Company to Apeiron for business referred to SMC and Koch by Apeiron. In connection with issuance of common stock in April 2019, the Company paid SMC and Koch an aggregate amount of $1.3 million of advisory fees, of which approximately $1.0 million was paid to Apeiron by SMC and Koch. In connection with 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 (See Note 11).

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 this agreement, for the twelve months ended December 31, 2021, the Company recorded $0.6 million of stock-based compensation included in general and administrative expense in its consolidated statement of operations. The Company also recorded $0.2 million of general and administrative expense in its consolidated statements of operations for the twelve months ended December 31, 2021 in connection with Mr. Angermayer's service as the Chairman of the supervisory board.

Voting Agreement with Hyperion Capital Ltd

On December 29, 2020, the Company entered into a voting agreement ("Voting Agreement") with Hyperion Capital Ltd. ("Hyperion"), a registered shareholder of COMPASS and an affiliate of Apeiron. Pursuant to the Voting Agreement, Hyperion appointed the Company as its lawful attorney to exercise the relevant rights (i.e. voting rights) attached to its certain ordinary shares in COMPASS (the "Shares"). In accordance with the Voting Agreement, Hyperion shall not transfer, assign or otherwise dispose of any of the shares without the prior written consent of the Company and the Voting Agreements will terminate when Hyperion no longer holds any of the Shares in COMPASS. Under the Voting Agreement, the Company will pay a quarterly fee of 5 basis points (on an annualized basis) of the volume weighted average price of COMPASS during such quarter, multiplied by the number of the Shares, with such quarterly fee subject to a step-up of 5 basis points per calendar quarter (capped at 20 basis points on an annualized basis) effective from April 1, 2021 and until the earlier of (i) the first anniversary of the initial public offering of the Company or (ii) March 31, 2022. In April 2021, the Voting Agreement was terminated and no fees were remitted to Hyperion for the years ended December 31, 2021 and 2020.

Neuronasal Promissory Note

In June 2020, the Company purchased a promissory note agreement with Neuronasal under which the Company provided $0.2 million to Neuronasal.

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. The Company made an immaterial amount of 401(k) contributions for the twelve months ended December 31, 2021 and 2020, respectively.

19. Subsequent Events

Dalriada License Agreement

In January 2022, in accordance with the Invyxis ESLA, Invyxis paid an upfront deposit of $1.1 million to Dalriada.

Loan to IntelGenx

In January 2022, the Company paid IntelGenx $3.0 million in connection with the amended and restated loan agreement. See Note 6 for additional discussion.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures.
Limitations on Effectiveness of Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports under 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 Chief Executive Officer and Chief 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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply 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, as of the end of the period covered by this Form 10-K, the effectiveness of our disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at reasonable assurance level as of December 31, 2021 as a result of the material weaknesses described below.

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 annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our consolidated financial statements for the fiscal years ended December 31, 2020 and 2021, we identified material weaknesses in our internal control over financial reporting. The material weaknesses that were 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. These deficiencies constitute material weaknesses in the design of our internal controls over financial reporting. As a result of the material weaknesses, we have relied, in part, on the assistance of outside advisors with expertise in these matters to assist us in the preparation of our consolidated financial statements and in our compliance with SEC reporting obligations and expect to continue to do so while we remediate these material weaknesses.

Management's Remediation Efforts

As disclosed herein, we have identified and begun to implement several steps, as further described below, designed to remediate the material weaknesses described in this Item 9A and to enhance our overall control environment. Although we intend to complete the remediation process as promptly as possible, we cannot at this time estimate how long it will take to remediate these material weaknesses, and our remediation plan may not prove to be successful. We will not consider the material weaknesses remediated until our enhanced controls are operational for a sufficient period of time and tested, enabling management to conclude that the enhanced controls are operating effectively. As of December 31, 2021, the material weaknesses had not been remediated.

Our remediation plan includes, but is not limited to, the following measures:

- Formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management.
- Hiring additional qualified accounting personnel and engaging consultants to enable the implementation of internal control over financial reporting and segregating duties amongst accounting personnel.
- Implementing certain accounting systems to automate manual processes.
- We will also continue to engage third parties as required to assist with technical accounting, application of new accounting standards, tax matters, and valuations of our equity instruments, contingent consideration, notes receivable and acquired in-process research and development.

While the foregoing measures are intended to effectively remediate the material weaknesses described in this Item 9A, it is possible that additional remediation steps will be necessary. As such, as we continue to evaluate and implement our plan to remediate the material weaknesses, our management may decide to take additional measures to address the material weaknesses or modify the remediation steps described above. Until these material weaknesses are remediated, we plan to continue to perform additional analyses and other procedures to help ensure that our consolidated financial statements are prepared in accordance with GAAP.

Management's Annual Report on Internal Control over Financial Reporting

This Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

We are taking actions to remediate the material weaknesses relating to our internal controls over financial reporting, as described above. Except as discussed above, there were no changes in our internal control over financial reporting (as that term is defined in Rules 13a-15(d) or 15d-15(d) of the Exchange Act) identified in management's evaluation pursuant to during the fiscal year ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.
None.

PART II- OTHER INFORMATION

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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2021.

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 waiver under our code of conduct in 2021.

Item 11. Executive Compensation.
The information required by this Item is incorporated by reference from our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2021.

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 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2021.

Item 14. Principal Accountant Fees and Services.
The information required by this Item is incorporated by reference from our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report

(a)(1) Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

(a)(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report or the notes thereto or is not applicable or required.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Articles of Association of ATAI Life Sciences N.V. (translated into English), currently in effect	10-Q	001-40493	3.1	8/16/2021	
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 Greg Weaver	S-1/A	333- 255383	10.2	6/11/2021	
10.3#	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	
10.25#	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#	Atai Life Sciences N.V. 2021 Incentive Award Plan	S-1/A	333- 255383	10.5	6/11/2021
10.17#	Form of Option Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.17	6/11/2021
10.18#	Form of Restricted Stock Award Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.18	6/11/2021
10.19#	Form of Restricted Stock Unit Agreement under 2021 Incentive Award Plan	S-1/A	333- 255383	10.19	6/11/2021
10.20#	2020 Employee, Director, and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.20	6/11/2021
10.21#	Form of Stock Option Agreement under 2020 Employee, Director and Consultant Equity Incentive Plan	S-1/A	333- 255383	10.21	6/11/2021
10.23#	Remuneration Policy for the Board of Supervisory Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.23	6/11/2021
10.24#	Remuneration policy for the Board of Managing Directors of ATAI Life Sciences N.V.	S-1/A	333- 255383	10.24	6/11/2021
10.7†	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
10.8†	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
10.9†	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
10.10†	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
10.11†	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

10.12†	Preferred Stock Purchase Agreement, dated as of December 23, 2019, among Neuronasal, Inc. and ATAI Life Sciences AG	S-1	333-255383	10.12	4/20/2021	
10.13†	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	
10.13†	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	
10.14†	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	
10.15#†	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	
10.16†	License and Collaboration Agreement, dated as of March 11, 2021, between Perception Neuroscience, Inc. and Otsuka Pharmaceutical Co., Ltd.	S-1/A	333-255383	10.16	5/27/2021	
10.22	Partnership Agreement of ATAI Life Sciences HSOP GbR, dated August 21, 2020	S-1/A	333-255383	10.22	6/11/2021	
10.26	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	
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, 2021 and 2020 and for each of the three years ended December 31, 2021, 2020 and 2019, 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.
# 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 30, 2022

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 30, 2022
/s/ Greg Weaver Greg Weaver	Chief Financial Officer and Managing Director (Principal Financial Officer and Principal Accounting Officer)	March 30, 2022
/s/ Christian Angermayer Christian Angermayer	Chairman of the Supervisory Board	March 30, 2022
/s/ Michael Auerbach Michael Auerbach	Supervisory Director	March 30, 2022
/s/ Jason Camm Jason Camm	Supervisory Director	March 30, 2022
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Supervisory Director	March 30, 2022
/s/ Amir Kalali Amir Kalali	Supervisory Director	March 30, 2022
/s/ Alexis de Rosnay Alexis de Rosnay	Supervisory Director	March 30, 2022
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Supervisory Director	March 30, 2022

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, 2021, 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.

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
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

The general meeting is presided over by the chairperson of the supervisory board or by the CEO or by the person designated thereto by the supervisory board, whether or not from its midst. If the chairperson and the CEO are absent and the supervisory board has not designated another person as aforesaid, the general meeting itself shall appoint its chairperson. Managing directors and supervisory directors may always attend a general meeting of shareholders. In these meetings, they have an advisory vote. The chairperson of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting of shareholders, to address the meeting and, in so far as they have such right, to vote pro rata to his or her shareholding. Shareholders may exercise these rights, if they are the holders of shares on the record date, if any, as required by Dutch law, which is currently the 28th day before the day of the general meeting of shareholders. Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting of shareholders. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Each common share confers the right on the holder to cast one vote at the general meeting of shareholders. Shareholders may vote by proxy. No votes may be cast at a general meeting of shareholders on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depositary receipts. Nonetheless, the holders of a right of use 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, the 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.

In accordance with our articles of association, for each general meeting, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting which must be published in a Dutch daily newspaper with national distribution at least 15 calendar days prior to the meeting (and such notice may therefore be published after the record date for such meeting). Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Delaware. Under the DGCL, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

The Netherlands. Pursuant to our articles of association, extraordinary general meetings will be held whenever required under Dutch law or whenever our management board or supervisory board deems such to be appropriate or necessary. Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law representing at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party or parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting. The court shall disallow the application of it does not appear that the requesting party or parties has/have previously requested our board to convene a general meeting of shareholders and or board has not taken the necessary steps so that the general meeting of shareholders could be held within six weeks after the request.

Also, the agenda for a general meeting shall include such items requested by one or more shareholders, and others with meeting rights under Dutch law, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our articles of association do not state such lower percentage. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting.

In accordance with the DCGC and our articles of association, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the

management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

The Netherlands. Under Dutch law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent, (ii) the company has not issued bearer shares or, with its cooperation, depository receipts for shares in its capital, and (iii) the resolution is adopted unanimously by all shareholders that are entitled to vote. Although our articles of association allow for shareholders' resolutions to be adopted in writing, the requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for us as a publicly traded company.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

The Netherlands. Subject to certain exceptions, Dutch law does not recognize the concept of appraisal or dissenters' rights. However, Dutch law does provide for squeeze-out procedures as described under "Dividends and Other Distributions — Squeeze-Out Procedures." Also, Dutch law provides for cash exit rights in certain situations for dissenting shareholders of a company organized under Dutch law entering into certain types of mergers. In those situations, a dissenting shareholder may file a claim with the Dutch company for compensation. Such compensation shall then be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the merger.

Delaware. The DGCL provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

The Netherlands. In the event a third-party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third-party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third-party in its own name. Dutch law provides for the possibility to initiate such actions collectively, in which a foundation or an association can act as a class representative and has standing to commence proceedings and claim damages if certain criteria are met. The court will first determine if those criteria are met. If so, the case will go forward as a class action on the merits after a period allowing class members to opt out from the case has lapsed. All members of the class who are residents of the Netherlands and who did not opt-out will be bound to the outcome of the case. Residents of other countries must actively opt in in order to be able to benefit from the class action. The defendant is not required to file defenses on the merits prior to the merits phase having commenced. It is possible for the parties to reach a settlement during the merits phase. Such a settlement can be approved by the court, which approval will then bind the members of the class, subject to a second opt-out. This new regime applies to claims brought after January 1, 2020 and which relate to certain events that occurred prior to that date. For other matters, the old Dutch

class actions regime will apply. Under the old regime, no monetary damages can be sought. Also, a judgment rendered under the old regime will not bind individual class members. Even though Dutch law does not provide for derivative suits, directors and officers can still be subject to liability under U.S. securities laws.

Delaware. Under the DGCL, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

The Netherlands. Under Dutch law, when issuing shares, a public company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company such as ours may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-in and called-up share capital plus any reserves required by Dutch law or its articles of association and (ii) the aggregate nominal value of shares of the company which the company acquires, holds or on which the company holds a pledge (*pandrecht*) or which are held by a subsidiary of the company, would not exceed 50% of its then-current issued share capital. Such company may only acquire its own shares if its general meeting has granted the management board the authority to effect such acquisitions.

An acquisition of common shares for a consideration must be authorized by our general meeting. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. The actual acquisition may only be effected pursuant to a resolution of our management board, with the approval of our supervisory board. Our management board, subject to approval by our supervisory board, is authorized, for a period of 18 months after we converted into the legal form of an N.V. to cause the repurchase of common shares by us of up to 20% of our issued share capital, for a price per share not exceeding 110% of the average market price of our common shares on Nasdaq (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by us). These shares may be used to deliver shares underlying awards granted pursuant to our equity-based compensation plans.

No authorization of the general meeting is required if fully paid common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee share purchase plan.

Delaware. Under the DGCL, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-Takeover Provisions

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

- a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital;

- a provision that our managing directors and supervisory directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient);

- a provision allowing, among other matters, the former chairman of our supervisory board or our former CEO, as applicable, to manage our affairs if all of our managing directors and supervisory directors are removed from office and to appoint others to be charged with the management and supervision of our affairs, until new managing directors and supervisory directors are appointed by the general meeting on the basis of a binding nomination discussed above; and

- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board.

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

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the DGCL also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the DGCL Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;

- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or

- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

The Netherlands. The management board and the supervisory board provide the general meeting, within a reasonable amount of time, all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of our company. If the management board or supervisory board invokes such an overriding interest, it must give reasons.

Delaware. Under the DGCL, any stockholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Dismissal of Directors

The Netherlands. Under our articles of association, the general meeting shall at all times be entitled to dismiss a managing director or supervisory director. The general meeting may only adopt a resolution to suspend or dismiss a managing director or supervisory director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board, in which latter case a simple majority is sufficient. The DCGC recommends that the general meeting can pass a resolution to dismiss a director by simple majority, representing no more than one-third of the issued share capital.

Delaware. Under the DGCL, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he or she is a part.

Issuance of Shares

The Netherlands. Under Dutch law, a company's general meeting is the corporate body authorized to resolve on the issuance of shares and the granting of rights to subscribe for shares. The general meeting can delegate such authority to another corporate body of the company, such as the management board, for a period not exceeding five years; this authorization may only be extended from time to time for a maximum period of five years. Our management board, with the approval of our supervisory board, is authorized, for a period of five years after we converted into the legal form of an N.V., to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time. We may not subscribe for our own shares on issue.

Delaware. All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

Preemptive Rights

The Netherlands. Under Dutch law, in the event of an issuance of common shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to employees or common shares issued against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for shares). Under our articles of association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting. Another corporate body, such as the management board, may restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting to restrict or exclude the preemptive rights or to designate another corporate body as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting. Our management board, with the approval of our supervisory board, is authorized, for a period not exceeding five years after we converted into the legal form of an N.V. to limit or exclude preemptive rights in relation to an issuance of shares or a grant of rights to subscribe for shares that the management board is authorized to resolve upon (see "Issuance of Shares" above).

Delaware. Under the DGCL, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

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

Under our articles of association, our management board, with the approval of our supervisory board, may decide that all or part of the profits are carried to reserves. After reservation of any profit, the remaining profit will be at the disposal of the general meeting for distribution, subject to restrictions of Dutch law and approval by our supervisory board. Our management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting, but only with the approval of the supervisory board. Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Delaware. Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

Shareholder Vote on Certain Reorganizations

The Netherlands. Under Dutch law, the general meeting must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one-third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

Delaware. Under the DGCL, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The DGCL permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the DGCL, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition,

stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Remuneration of Managing Directors and Supervisory Directors

The Netherlands. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our directors, provided that such compensation is consistent with our compensation policy. Changes to such compensation policy will require a vote of our general meeting by simple majority of the votes cast. The supervisory board determines the remuneration of individual managing directors with due observance of the compensation policy at the recommendation of our compensation committee. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the managing directors and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting.

Delaware. Under the DGCL, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of the compensation policy may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law.

Exhibit 21.1

Subsidiaries of the Registrant

Name	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
Neuronasal, 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- 257482 on Form S-8 of our report dated March 30, 2022, 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, 2021.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

March 30, 2022

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-257482) of ATAI Life Sciences N.V. of our report dated February 24, 2022 relating to the financial statements and the effectiveness of internal control over financial reporting of COMPASS Pathways plc, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Reading, United Kingdom

March 30, 2022

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)) 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) [omitted];

   (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, 30, 2022

By: /s/ Florian Brand
Florian Brand
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Greg Weaver, 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)) 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) [omitted];
   (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 30, 2022

By: /s/ Greg Weaver
Greg Weaver
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, 2021 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 30, 2022

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, 2021 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 30, 2022

By: /s/ Greg Weaver
Greg Weaver
Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

COMPASS Management Evaluation of Controls & Procedures

Evaluation of Disclosure Controls and Procedures
Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2021. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2021 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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 Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
Under the supervision and with the participation of our management, including Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria) . Based on our evaluation under that framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.
The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting
There were no changes in our internal control over financial reporting during the year ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Exhibit 99.1

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

INDEX TO ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

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, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of convertible preferred shares and shareholders' equity (deficit), and of cash flows for each of the three years in the period ended December 31, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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, 2021 and 2020**,** and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

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

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing elsewhere in this exhibit 99.1. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based

on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 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, 2021, the Company recognized $9.6 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 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) a 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 included testing the effectiveness of controls over management's process relating to accruing the benefit from R&D tax credit. 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 (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 24, 2022

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,	
	2021	2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 273,243	$ 190,327
Restricted cash	104	29
Prepaid income tax	332	—
Prepaid expenses and other current assets	21,621	12,048
Total current assets	295,300	202,404
NON-CURRENT ASSETS:		
Investment	525	529
Property and equipment, net	398	245
Operating lease right-of-use assets	3,696	—
Deferred tax assets	766	221
Other assets	213	57
Total assets	$ 300,898	$ 203,456
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,564	$ 2,747
Accrued expenses and other liabilities	10,308	4,148
Operating lease liabilities - current	2,235	—
Total current liabilities	15,107	6,895
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	1,379	—
Total liabilities	16,486	6,895
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,019,874 and 35,930,331 shares authorized, issued and outstanding at December 31, 2021 and 2020, respectively	435	367
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at December 31, 2021 and 2020	28	28
Additional paid-in capital	444,750	279,480
Accumulated other comprehensive income	8,840	14,585
Accumulated deficit	(169,641)	(97,899)
Total shareholders' equity	284,412	196,561
Total liabilities and shareholders' equity	$ 300,898	$ 203,456

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)

	Year Ended December 31,		
	2021	**2020**	**2019**
OPERATING EXPENSES:			
Research and development	$ 44,027	$ 23,366	$ 12,563
General and administrative	39,194	28,027	8,616
Total operating expenses	83,221	51,393	21,179
LOSS FROM OPERATIONS:	(83,221)	(51,393)	(21,179)
OTHER INCOME (EXPENSE), NET:			
Other income, net	40	319	73
Foreign exchange gains (losses)	1,990	(11,702)	(81)
Fair value change of convertible notes	—	(1,041)	(670)
Fair value change of convertible notes - due to a related party	—	(730)	(469)
Benefit from R&D tax credit	9,648	4,245	2,729
Total other income (expense), net	11,678	(8,909)	1,582
Loss before income taxes	(71,543)	(60,302)	(19,597)
Income tax expense	(199)	(32)	(15)
Net loss	(71,742)	(60,334)	(19,612)
Other comprehensive income:			
Foreign exchange translation adjustment	(5,745)	14,683	337
Comprehensive loss	(77,487)	(45,651)	(19,275)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (1.79)	$ (3.55)	$ (2.62)
Weighted average ordinary shares outstanding—basic and diluted	39,997,587	16,991,664	7,476,422

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

COMPASS PATHWAYS PLC

Consolidated Statements of Convertible Preferred Shares and Shareholders' Equity (Deficit)

(in thousands, except share and per share amounts)

	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 INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2018	**2,650,980**	**$ 3,761**	**7,131,525**	**$ 35,147**	**—**	**$ —**	**10,551,166**	**$ 111**	**—**	**$ —**	**$ 3,909**	**$ (435)**	**$ (17,953)**	**$ (14,368)**
Issuance of ordinary shares, net of issuance costs	—	—	—	—	—	—	201,263	—	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,253	—	—	3,253
Unrealized gain (loss) on foreign currency translation	—	—	—	—	—	—	—	—	—	—	—	337	—	337
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(19,612)	(19,612)
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 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
Vesting of restricted stock units	—	—	—	—	—	—	12,607	—	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	8,639	—	—	8,639
Unrealized 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**

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

COMPASS PATHWAYS PLC
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2021	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (71,742)	$ (60,334)	$ (19,612)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	175	112	63
Non-cash loss on foreign currency remeasurement	22	—	—
Change in fair value of convertible notes	—	1,771	1,139
Non-cash share-based compensation	8,639	17,983	3,253
Non-cash lease expenses	1,797	—	—
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(8,984)	(4,490)	(3,430)
Deferred and prepaid tax assets	(877)	(221)	—
Other assets	(160)	(57)	—
Operating lease liabilities	(1,880)	—	—
Accounts payable	(163)	1,303	580
Accrued expenses and other liabilities	5,428	2,553	194
Net cash used in operating activities	(67,745)	(41,380)	(17,813)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(334)	(131)	(165)
Purchase of investments	—	(497)	—
Net cash used in investing activities	(334)	(628)	(165)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds of issuance of ordinary shares, net of issuance costs	154,794	—	—
Proceeds from exercise of options	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	—
Proceeds from issuance of convertible notes	—	—	18,434
Payments of initial public offering costs	—	—	(55)
Net cash provided by financing activities	156,646	194,155	18,379
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(5,576)	13,225	1,676
Net increase in cash and cash equivalents	82,991	165,372	2,077
Cash, cash equivalents and restricted cash, beginning of the year	190,356	24,984	22,907
Cash, cash equivalents and restricted cash, end of the year	$ 273,347	$ 190,356	$ 24,984
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			

Right-of-use assets obtained in exchange for new operating lease liabilities	$ 5,562	$ —	$ —
Proceeds from exercise of options were not received and recorded in other current assets	$ 53	$ —	$ —
Deferred issuance costs included in prepaid expenses	$ 856	$ —	$ 58
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,		
	2021	2020	2019
Cash and cash equivalents	$ 273,243	$ 190,327	$ 24,966
Short-term restricted cash	104	29	18
Total cash, cash equivalents and restricted cash	$ 273,347	$ 190,356	$ 24,984

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 psilocybin therapy through late-stage clinical trials in Europe and North America for patients with treatment-resistant depression.

The Company is a public limited company incorporated in England and Wales and was originally incorporated under the name COMPASS Rx Limited before being renamed COMPASS Pathways plc as part of our corporate reorganization as more particularly described below. Prior to and in contemplation of the consummation of the Company's initial public offering, or IPO, of American Depositary Shares, or ADSs, the Company undertook a corporate reorganization. The corporate reorganization took place in several steps, all of which have been completed. The Company refers to the following steps, which are discussed in more detail below, as the "corporate reorganization".

•Prior to the corporate reorganization, the holding company of the COMPASS group was COMPASS Pathfinder Holdings Limited.

• Pursuant to the terms of a share for share exchange completed on August 7, 2020, all of the shareholders of COMPASS Pathfinder Holdings Limited, which, until the corporate reorganization was the holding company of the COMPASS group, exchanged each of the shares held by them for 1,161 of the same class, with the same shareholder rights, of newly issued shares of COMPASS Rx Limited and, as a result, COMPASS Pathfinder Holdings Limited became a wholly owned subsidiary of COMPASS Rx Limited. This share exchange had the effect of a 1:1,161 share split. No shareholder rights or preferences changed as a result of the share for share exchange. COMPASS Pathfinder Holdings Limited is a private limited liability company incorporated under the laws of England and Wales and its primary offices are in London, United Kingdom, (U.K.). COMPASS Pathfinder Holdings Limited has one wholly-owned subsidiary, COMPASS Pathfinder Limited, whose primary office is in London, United Kingdom. COMPASS Pathfinder Limited has one wholly-owned subsidiary, COMPASS Pathways Inc. whose primary office is located in New York, United States of America.

• Pursuant to Part 17 of the Companies Act 2006, on August 19, 2020, COMPASS Rx Limited reduced its share capital by way of a reduction of the nominal value of each share in the capital of COMPASS Rx Limited from £1.00 to £0.001 in order to satisfy the net asset test requirement in section 92 of the Companies Act 2006 for the re-registration of COMPASS Rx Limited as a public limited company and to create distributable reserves in order to support future distributions activities by the Company (although we note that none are currently planned).

• COMPASS Rx Limited was re-registered as a public limited company and renamed COMPASS Pathways plc, effective on August 21, 2020. COMPASS Pathways plc is a holding company with nominal activity.

• Immediately prior to the completion of the Company's IPO on September 22, 2020, the different classes of issued share capital of COMPASS Pathways plc were reorganized on a one-for-0.1136 basis into a single class of 27,305,331 ordinary shares by way of a reverse share split, which was retroactively restated in our consolidated financial statements. As part of this reverse share split, the nominal value of COMPASS Pathways plc's ordinary shares changed from £0.001 per share to £0.008 per share and a single, non-voting deferred share with a nominal value of £21,921.504 in the capital of the Company was created and transferred to the Company.

• On September 22, 2020, the Company completed the IPO. In the IPO, the Company sold an aggregate of 8,625,000 ADSs representing the same number of ordinary shares, including 1,125,000 ADSs pursuant to the underwriters'

over-allotment right option to purchase additional ADSs, at a public offering price of $17.00 per ADS. Net proceeds were approximately $132.8 million, after deducting underwriting discounts and commissions and other offering expenses.

COMPASS Pathways plc is a continuation of COMPASS Pathfinder Holdings Limited and its subsidiaries, and the corporate reorganization has been accounted for as a combination of entities under common control. The corporate reorganization associated with the IPO was given retrospective effect in the prior year consolidated financial statements and such financial statements represent the financial statements of COMPASS Pathways plc. In connection with the corporate reorganization, outstanding restricted share awards and option grants of COMPASS Pathfinder Holdings Limited were exchanged for share awards and option grants of COMPASS Pathways plc with identical restrictions.

The Company is subject to risks and uncertainties common to early-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 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 in connection with the September 2020 IPO and its $154.8 million May 2021 follow-on offering, including the underwriters' exercise of their over-allotment option. On October 8, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC ("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 our ADSs, if any, will be made at market prices. We have not yet sold any ADSs under this at-the-market offering. The Company has incurred recurring losses since its inception, including net losses of $71.7 million and $60.3 million for the year ended December 31, 2021 and 2020, respectively. In addition, as of December 31, 2021, the Company had an accumulated deficit of $169.6 million. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. 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 Company believes the cash and cash equivalents on hand as of December 31, 2021 of $273.2 million will be sufficient to fund its operating expenses and capital expenditure requirements into 2024.

The Company continues to assess its business plans and the impact which the ongoing COVID-19 pandemic may have on its ability to advance the development and manufacturing of COMP360 as a result of adverse impacts on the research sites, service providers, vendors, or suppliers on whom it relies, or to raise further financing to support the development of its investigational COMP360 psilocybin therapy. No assurances can be given that this analysis will enable the Company to avoid any future impact from the ongoing COVID-19 pandemic or the emergence of new variants, including downturns in business sentiment generally or in its sector in particular. The Company cannot currently predict the scope and severity of any future potential business shutdowns or disruptions, but if the Company or any of the third parties on whom it relies or with whom the Company conducts business were to experience additional shutdowns or other business disruptions, the Company's ability to conduct its business in the manner and on the timelines presently planned could be materially and adversely impacted.

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 in 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, discount rates for leases, the fair value of ordinary shares before IPO, share-based compensation, measurement of the fair value of the Company's convertible notes 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 cash equivalents.

Restricted Cash

Restricted cash as of December 31, 2021 and 2020 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 of Financial Instruments

Certain 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 first two are considered observable and the last is 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 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, 2021 and 2020.

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, views the Company's operations and manages its business as a single operating segment; however, the Company operates in two geographic regions: the 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 cancelable, 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 accrued liabilities, 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 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 ordinary shares. The measurement date for employee and non-employee awards is the date of grant, and share-based compensation costs are recognized as 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, we launched the Share Incentive Plan (the "SIP") and Employee Share Purchase Plan (the "ESPP"), through which employees can purchase shares at a discounted price. We 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.

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, 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. 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 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 the grant.

The OPM method 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. 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 sheet. 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. Prospectively, the Company will adjust 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 $2.0 million and foreign exchange losses of approximately $11.7 million for the years ended December 31, 2021 and 2020, respectively. These gains and losses arise from US 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 and shareholders' equity (deficit) 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 (deficit).

Income Taxes

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 on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities substantively 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 benefits 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, 2021 and 2020, the Company has not identified any 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, 2021 and 2020 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, 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. Further, changes to the EU State Aid cap to limit the total aid claimable in respect of a given project to €7.5 million may impact the Company's ability to claim R&D tax credits in future.

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 (deficit) that result from transactions and economic events other than those with shareholders. For the years ended December 31, 2021 and 2020, the 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 ordinary shares, share options, convertible preferred, Series A convertible preferred shares and Series B convertible preferred shares, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. 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.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, Changes to the Disclosure Requirements for Fair Value Measurement, or ASU 2018-13, which amends changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty which should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. ASU 2018-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those periods. Early application is permitted. The Company adopted this ASU as of January 1, 2020 and it has no material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The new standard will align the requirements for capitalizing implementation costs for hosting arrangements (services) with costs for internal-use software (assets). As a result, certain implementation costs incurred in hosting arrangements will be deferred and amortized. The new standard was effective for the Company on January 1, 2020. The Company adopted this ASU as of January 1, 2020 and an immaterial amount of implementation costs were capitalized within other assets as of December 31, 2020.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), as subsequently amended, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors), and replaces the existing guidance in ASC 840. The FASB has issued several updates to the standard which: (i) clarify how to apply certain aspects of the new standard; (ii) provide an additional transition method for adoption of the new standard; (iii) provide a practical expedient for certain lessor accounting; and (iv) amend certain narrow aspects of the guidance. The new standard requires the identification and classification of arrangements that are or contain a lease and requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine the recognition pattern of lease expense over the term of the lease. In addition, a lessee is required to record (i) a right-of-use asset and a lease liability on its balance sheet for all leases with accounting lease terms of more than 12 months regardless of whether it is an operating or finance lease and (ii) lease expense in its consolidated statements of operations and comprehensive loss for operating leases and amortization and interest expense in its consolidated statements of operations and comprehensive loss for financing leases. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases under ASC 840. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), which added an optional transition method that allows companies to adopt the standard as of the beginning of the year of adoption as opposed to the earliest comparative period presented. This guidance is effective for Emerging Growth Companies for annual periods beginning after December 15, 2021, including interim periods within that fiscal year. Early adoption is permitted.

The Company lost its Emerging Growth Company status on December 31, 2021 and has adopted Topic 842 during the year-ended December 31, 2021, with an effective adoption date of January 1, 2021. Interim periods previously issued for fiscal year 2021 were reported under the legacy leasing guidance of ASC 840. The Company has elected to adopt ASC 842 by utilizing the effective date method, which resulted in a cumulative-effect adjustment to the Company's consolidated balance sheets at January 1, 2021 . As a result, prior periods are presented in accordance with the previous guidance in 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, (3) or 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 year ended December 31, 2021.

In December 2019, the Financial Accounting Standard Board, or 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.

3. Fair Value Measurements

There are no financial instruments measured at fair value on a recurring basis as of December 31, 2021 and 2020. Management believes that the carrying amounts of the Company's consolidated financial instruments, including 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 and $1.1 million for changes in the fair value of the convertible notes in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2020 and 2019, respectively.

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, 2018	$ —
Issuance of convertible notes	18,434
Change in fair value	1,139
Exchange difference	1,516
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 and 2021	$ —

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 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, 2021, 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,	
	2021	2020
UK R&D tax credit	$ 9,587	$ 4,610
Prepaid insurance premium	3,359	3,154
Prepaid research and development	4,562	2,317
VAT recoverable	1,629	1,171
Deferred offering costs	840	—
Security deposit	274	287
Other current assets	1,370	509
	$ 21,621	$ 12,048

6. Property and Equipment, Net

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

	December 31,	
	2021	**2020**
Lab equipment	$ 370	$ 130
Office equipment	315	260
Furniture and fixtures	65	37
Leasehold improvements	6	6
	756	433
Less: accumulated depreciation	(358)	(188)
	$ 398	$ 245

Depreciation and amortization expense were $0.2 million for the year ended December 31, 2021 and $0.1 million for the years ended December 31 2020 and 2019.

7. Accrued Expenses and Other Liabilities

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

	December 31,	
	2021	2020
Accrued research and development expense	$ 3,043	$ 720
Accrued professional expenses	1,386	701
Accrued compensation and benefit costs	5,018	1,687
Payroll tax payable	593	384
Income taxes payable	—	243
Other liabilities	268	413
	$ 10,308	$ 4,148

8. Convertible Notes

On August 28, 2019, the Company entered into convertible note agreements for a total additional principal amount of $18.4 million (£15.0 million). The convertible notes issued in 2019 are collectively referred to as the "2019 Convertible Notes". The 2019 Convertible Notes bore interest at 3% per annum and were payable concurrently with repayment of the principal amount. No repayment of principal or interest was due until maturity, which occurred 12 months after issuance of the 2019 Convertible Notes. Under the agreement, the 2019 Convertible Notes automatically converted upon a Qualified Financing and Non-Qualified Financing securities upon (i) the completion of a Qualified Financing; or (ii) noteholder majority had approved a Non-Qualified Financing constituting a conversion event, at 15% discount of the per share price of the securities sold in either a Qualified Financing or Non-Qualified Financing.

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 and $1.1 million as change in fair value of the convertible notes during the years ended December 31, 2020 and 2019. There are no convertible notes outstanding in the year ended December 31, 2021.

9. Convertible Preferred Shares

Prior to the IPO, the Company had issued convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares.

In August 2017, the Company entered into a subscription and shareholders agreement, or the 2017 Agreements, pursuant to which the Company issued an aggregate of 2,650,980 convertible preferred shares for total proceeds of approximately $3.9 million and incurred issuance costs of $0.1 million, recorded as a reduction to convertible preferred shares.

The 2017 Agreements were amended and restated in September 2018, as so amended, the Amended 2018 Agreements. Pursuant to the Amended 2018 Agreements, the Company issued 7,131,525 Series A convertible preferred shares for an aggregate purchase price of $35.4 million and incurred issuance costs of $0.3 million, recorded as a reduction to 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 shares of convertible preferred shares, Series A convertible preferred shares and Series B convertible preferred shares into ordinary shares.

10. Ordinary Shares

In August 2017, the Company issued 10,551,166 ordinary shares for services rendered to the Company at a nominal value of £0.008 per share. In connection with the issuance of convertible preferred shares in August 2017, vesting conditions were placed on the 10,551,166 shares. These shares vested as follows: 25% of the shares held by certain of the founders vested on August 17, 2017; 25% of the shares vested on August 17, 2018; and 50% of shares vested in twenty-four equal monthly installments from August 17, 2018 through August 17, 2020. The fair value of the ordinary shares issued to certain of the founders in excess of the consideration initially paid was recognized as share-based compensation over the vesting period.

In October 2019, the Company issued 102,214 and 99,049 ordinary shares to a non-employee and an employee, with the vesting period of three and four years, respectively. The employee left the Company in July 2020 and 63,972 ordinary shares were forfeited and repurchased by the Company.

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.

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, 2021, 70,482 restricted share units vested, of which, 12,607 ordinary shares were issued in settlement of the vested restricted shares units on August 13, 2021. No ordinary shares were issued for the vested restricted share units of 57,875 in May, August and November 2021.

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, 2021, no cash dividends had been declared or paid by the Company.

11. Share-Based Compensation

2017 Equity Incentive Plan

Under the Company's shareholder and subscription agreements, the Company is 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 are in the form of share options, the options are 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 provides 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 is administered by the board of directors.

As of December 31, 2021, the Company was authorized under the shareholder agreements to issue a total of 13,601,246 ordinary shares, including shares underlying options granted pursuant to the 2017 Plan. Forfeitures are accounted for as they occur. As of December 31, 2021, there were 514,075 shares available for issuance as incentives to the Company's employees and directors, which includes shares underlying options that may be granted from time to time subsequent to December 31, 2021 under the terms of the 2017 Plan. 12,607 ordinary shares were issued for 70,482 restricted share units that vested during the year ended December 31, 2021.

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. 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. The options granted by the Company prior to April 17, 2020 contain provisions that to the extent then outstanding, they will be subject to accelerated vesting upon the occurrence of a Sale, Asset Sale or listing of the Company's ordinary shares on any stock exchange, and any such unvested options accordingly became fully vested upon a Listing (as such term is defined in the 2017 Plan). 1,015,813 options granted to the President and Chief Business officer of the Company on May 19, 2020 became fully vested on August 17, 2020, resulting in the recognition of $9.5 million in share-based compensation expense, including $2.4 million in research and development expenses and $7.1 million in general and administrative expenses.

The options granted before June 30, 2020 are subject to 100% vesting upon the date of the listing of the Company's ordinary shares on any stock exchange. The options granted on June 30, 2020 are 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. Upon completion of the IPO, 866,268 options vested due to the accelerated vesting and a total of $3.5 million was immediately recognized in share-based compensation expense, including $1.4 million in research and development expenses and $2.1 million in general and administrative expenses.

The options granted on June 30, 2020 are 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 are 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. Options granted under the 2017 Plan generally expire 10 years from the date of grant.

2020 Employee Share Purchase Plan

The Company's 2020 Employee Share Purchase Plan, or 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 reserves and authorizes 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 January 1, 2022, by the lesser of (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31 or (ii) 510,058 ordinary shares. 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 Share Incentive Plan (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 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 award 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 was 2,074,325 shares as of December 31, 2021, of which 406,737 shares remained available for future grant.

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

Ordinary Shares

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2019	1,907,515	$ 0.74
Granted	—	—
Vested	(1,829,786)	0.69
Forfeited	(63,972)	0.05
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, 2021	—	$ —

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

Restricted Share Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested and Outstanding as of December 31, 2019	—	$ —
Granted	257,708	10.19
Vested	—	—
Forfeited	(40,226)	10.19
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

As of December 31, 2021 and 2020, there was $1.2 million and $2.0 million of unrecognized compensation cost related to unvested restricted share units, which is expected to be recognized over a weighted-average period of 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 year ended December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	1,539,411	$ 0.82	9.58	$ 2,284
Granted	3,405,490	$ 7.17		
Exercised	(429,929)	$ 0.05		
Cancelled or forfeited	(84,632)	$ 9.87		
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		
Forfeited	(313,830)	$ 22.45		
Outstanding as of December 31, 2021	3,915,503	$ 13.53	8.64	$ 51,162
Exercisable as of December 31, 2021	2,225,758	$ 3.13	8.24	$ 43,457
Unvested as of December 31, 2021	1,689,745	$ 26.63	9.16	$ 7,705

During the year ended December 31, 2020, 429,929 share options were exercised, of which 232,227 share options were exercised by certain optionees with a total exercise price of less than $0.1 million. These ordinary shares were not issued to those optionees by December 31, 2020 and the amount received by the Company was recorded in the additional paid-in capital as at that date.

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

The weighted average exercise price of options granted to UK employees during the year ended December 31, 2020 was $7.17 per share. The weighted average exercise price of options granted to United States employees during the year ended December 31, 2020 was $5.17 per share. During the year ended December 31, 2021, there was no difference between the exercise price of UK employees and US employees if the options were granted on the same day.

The weighted average exercise price of options granted to UK employees during the year ended December 31, 2019 was less than $0.01 per share. The weighted average exercise price of options granted to United States employees during the year ended December 31, 2019 was $1.39 per share.

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 $21.35, $9.83 and $1.88 per share during the years ended December 31, 2021, 2020 and 2019, respectively.

As of December 31, 2021 and 2020, there was $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 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, 2021, 2020 and 2019 were as follows:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.73 years	5.95 years	5.90 years
Expected volatility	67.36 %	66.10 %	63.40 %
Risk-free interest rate	0.95 %	0.43 %	1.88 %
Expected dividend yield	— %	— %	— %
Fair value of underlying ordinary shares	$ 35.21	$ 12.58	$ 2.16

Share-based Compensation Expense

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

	Years Ended December 31,		
	2021	2020	2019
Research and development	4,569	6,336	1,817
General and administrative	4,070	11,647	1,436
	$ 8,639	$ 17,983	$ 3,253

In December 2021, the Company amended the initial share option contract with one employee. The amendment did not result in a modification and there was no impact on the total share-based compensation expenses recorded.

12. Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
United Kingdom	(72,397)	(60,522)	(19,619)
Foreign	854	220	22
Loss before provision for income taxes	(71,543)	(60,302)	(19,597)

The provision for income taxes for the years ended December 31, 2021, 2020 and 2019 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,		
	2021	2020	2019
Current income tax provision			
United Kingdom	$ —	$ —	$ —
Foreign	744	253	15
Total current expense:	$ 744	$ 253	$ 15
Deferred income tax benefit:			
United Kingdom	—	—	—
Foreign	(545)	(221)	—
Total deferred income tax benefit:	(545)	(221)	—
Total provision for income taxes	$ 199	$ 32	$ 15

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,		
	2021	2020	2019
Income taxes at UK statutory rate	$ (13,592)	$ (11,458)	$ (3,724)
Permanent differences	69	340	238
UK R&D tax credit	3,747	1,664	1,036
Change in valuation allowance	29,180	8,683	2,205
State income taxes	1	(5)	5
Deferred tax asset true-up	80	919	—
Equity Compensation	(8,302)	—	—
Change in UK Tax Rate	(10,147)	—	—
Other	(837)	(111)	255
	$ 199	$ 32	$ 15

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2020 and 2019 consist of the following (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Net operating loss carryforward	$ 35,947	$ 10,075	$ 2,936
Reserves and accruals	169	62	757
Share-based compensation	6,232	3,128	2
Total deferred tax assets	42,348	10,137	3,693
Valuation allowance	$ (41,483)	$ (13,000)	$ (3,665)
Depreciation	(99)	(44)	(30)
Total deferred tax liabilities	(99)	3,084	(28)
Net deferred tax assets	$ 766	$ 221	$ —

As of December 31, 2021, 2020 and 2019, the Company had UK net operating loss carryforwards of approximately $144.0 million, $53.0 million and $17.7 million, respectively, that can be carried forward indefinitely.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2021, 2020 and 2019 related primarily to the increases in net operating loss and were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Valuation allowance at beginning of year	$ 13,000	$ 3,665	$ 1,321
Increases recorded to income tax provision	29,180	8,683	2,344
Increases recorded to CTA	—	652	—
Decreases recorded to CTA	(697)	—	—
Valuation allowance at end of year	$ 41,483	$ 13,000	$ 3,665

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, 2021, 2020 and 2019, 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, 2021, 2020 and 2019. 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, 2021, 2020 and 2019.

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, 2021, 2020 and 2019, 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,		
	2021	2020	2019
Numerator			
Net loss	$ (71,742)	$ (60,334)	$ (19,612)
Net loss attributable to ordinary shareholders - basic and diluted	$ (71,742)	$ (60,334)	$ (19,612)
Denominator			
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	39,997,587	16,991,664	7,476,422
Net loss per share - basic and diluted	$ (1.79)	$ (3.55)	$ (2.62)

The Company's potentially dilutive securities, which include unvested ordinary shares, unvested restricted share units, convertible preferred shares, Series A convertible preferred shares, Series B convertible preferred shares 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 year end, from the computation of diluted net loss per share attributable to ordinary shareholders for the years ended December 31, 2021, 2020 and 2019 because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2021	2020	2019
Unvested ordinary shares	—	13,757	—
Unvested restricted share units	115,140	217,482	—
Convertible preferred shares	—	—	2,650,980
Series A convertible preferred shares	—	—	7,131,525
Vested restricted share units for which shares are not in issue	57,875	—	—
Share options	3,915,503	4,430,340	1,539,411
	4,088,518	4,661,579	11,321,916

14. Right of use of assets:

Eastbourne Terrace, London, UK

In November 2019, the Company entered into an operating lease located at 19 Eastbourne Terrace, London, UK. This lease commenced on January 1, 2020, and expired on December 31, 2021. Under the terms of the lease, the Company paid £780,000 per year, and paid a refundable deposit of £130,000 upon signing the agreement. Additionally, in February 2021, the Company entered into an Amendment for rental relief in January and February 2021 for a total of £32,500, due to extended periods working from home as a result of the COVID-19 pandemic.

New York, NY

In May 2019, the Company entered into a lease with BioLabs for 200 rentable square feet ("sf") of office space at 180 Varick Street, New York, New York 10014, United States. The lease is cancellable with 30 days' notice. This lease 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.

San Francisco, CA

In August 2021, the Company entered into an operating lease commencing in August 2021 for approximately 2,526 rentable square feet located in San Francisco, California. The lease is set to expire on August 31, 2022 with no option to renew. The total monthly rent for the lease term is $10,000 per month, and the Company paid $9,000 of advanced rent upon lease execution. Additionally, the Company paid a refundable security deposit of $20,000 upon execution of the lease.

The following table summarizes our costs included in consolidated statements of operations and comprehensive loss related to right of use lease assets we have entered into through December 31, 2021:

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

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2021 (in thousands):

Year Ended December 31,	Amount
2022	$ 2,285
2023	1,471
Total lease payments	3,756
Less: imputed interest	(142)
Total	$ 3,614

The Company recorded rent expense totaling $1.9 million, $1.0 million and $0.4 million for the years ended December 31, 2021, 2020 and 2019, respectively.

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, 2021, 2020 or 2019.

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. Related Party Transactions

On August 28, 2019, as part of the Company's 2019 Convertible Notes issuance an amount of $7.6 million (£6.2 million) was issued to a shareholder and it was converted to 710,621 shares of Series B convertible preferred shares on April 17, 2020. As of December 31, 2019, the shareholder's convertible loan note remained outstanding. Refer to Note 8 for additional information on the 2019 Convertible Notes.

The Company receives accounting and professional services from Tapestry Networks, Inc., or Tapestry, a company affiliated with a director of the Company and the Company's Chief Executive Officer, from time to time as needed. The Company recorded accounting and professional fees of $0.1 million and $0.1 million for the years ended December 31, 2021 and 2020 and $0.2 million for year end December 31, 2019. As of December 31, 2021 and 2020, the Company had less than $0.1 million outstanding to Tapestry.

17. 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, less than $0.1 million and $0.1 million in contributions for the years ended December 31, 2021, 2020 and 2019, 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 $0.1 million, less than $0.1 million and nil in contributions in the years ended December 31, 2021, 2020 and 2019, respectively.