ANNUAL REPORT

FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2023

ATAI LIFE SCIENCES N.V.

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BOARD REPORT

Introduction
In this report, the terms “atai”, “we”, “us”, “our”, “the Group” and “the company” refer to atai Life Sciences N.V. and, where appropriate, its subsidiaries. Unless state otherwise, information presented in this report is at 31 December 2023.

This report has been prepared by atai’s management board (the “management board”) and has been approved by atai’s supervisory board (the “supervisory board”) pursuant to Section 2:391 of the Dutch Civil Code (“DCC”) and also contains (i) atai’s Dutch statutory annual accounts as defined in Section 2:361(1) DCC and (ii) the information to be added pursuant to Section 2:392 DCC (to the extent relevant).

atai has its registered office and its place of business at Wallstraße 16, 10179 Berlin, Germany. Its statutory seat is in Amsterdam, Netherlands, and the company is registered in the Trade Register at the Chamber of Commerce under number CvC 80299776.

Our office address and our principal executive office is located at Wallstraße 16, 10179 Berlin, Germany, and our telephone number is +49 89 2153 9035. Our website address is www.atai.life.

Preparation
The Financial statements included herein have been prepared in accordance with the International Financial Reporting Standards, as adopted by the European Commission (“EU IFRS”). This Report related to the fiscal year ended 31 December 2023 and, unless explicitly stated otherwise, information presented in this Report is at 31 December 2023.

Cautionary note regarding forward looking statements
This report contains forward-looking statements. All statements contained in this report other than statements of historical fact should be considered forward-looking statements, including without limitation statements regarding our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue; the timing of and our ability to obtain and maintain regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents and short-term investments to fund our operations; available funding under the Hercules Capital, Inc. loan facility; and the plans and objectives of management for future operations and capital expenditures. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “could,” “would,” “project,” “plan,” “potentially,” “preliminary,” “likely,” and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described under "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 report.

Any forward-looking statements made herein speak only as of the date of this report, 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 Report or to conform these statements to actual results or revised expectations.

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

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

Mental health disorders such as depression, substance use disorder, and anxiety, which are among our initial focus indications, are highly prevalent and estimated to affect more than one billion people globally. In addition, the total costs of mental health disorders are significant and expected to increase substantially. Between 2009 and 2019, spending on mental health care in the United States increased by more than 50%, reaching $225 billion, and a Lancet Commission report estimates the global economic cost will reach $16 trillion by 2030. While current treatments, such as selective serotonin reuptake inhibitors, or SSRIs, and serotonin-norepinephrine reuptake inhibitors, or SNRIs, are well established and effective for certain patients, a significant percentage of patients either respond inadequately or relapse, translating to a significant unmet patient need.

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

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

Our Programs
We have built a diversified pipeline of drug and discovery development programs, including psychedelic and nonpsychedelic compounds. Psychedelics are emerging as novel breakthrough therapies for mental health disorders, such as depression and, with growing scientific support, recent regulatory advancements and increasing patient and physician acceptance. There is a growing body of clinical evidence that supports the potential efficacy and safety profile of psychedelics, which may have potential therapeutic benefits, such as a rapid onset of effect and sustained efficacy after a short-course of administration. We believe these programs, which include new molecular entities as well as variants of known compounds with unique pharmacology, have the potential to address unmet needs in mental health disorders.

These programs vary across stage of development, indication and mechanism of action, which we believe will improve the commercial potential and risk profile of our pipeline in the aggregate. We also prioritize the development of compounds and compound classes that have shown potential for efficacy and safety in prior clinical trials or observational studies.

Our Strategic Investments
COMPASS Pathways plc (“COMPASS”) is developing its investigational COMP360 psilocybin therapy, which comprises administration of COMP360 with psychological support from specially trained therapists, with an initial focus on treatment-resistant depression (“TRD”). COMPASS is currently conducting a Phase 3 pivotal program composed of two pivotal trials, each of which will have a long-term follow-up component. Top-line

pivotal data for the first and second trials are expected in the fourth quarter of 2024 and mid-2025, respectively. As of December 31, 2023, we beneficially owned 9,565,774 shares representing a 15.4% equity interest in COMPASS. Certain of our founding investors were also seed investors and/or founders of COMPASS. Our interest in the product candidates of COMPASS is limited to the potential appreciation of our equity interest.

Beckley Psytech Limited ("Beckley Psytech") is developing its investigational compounds, BPL-003 5 Methoxy N,N-dimethyltryptamine benzoate ("5-MEO-DMT") for treatment of TRD and Alcohol Use Disorder ("AUD") and ELE-101 psilocin therapy for the treatment of Major Depressive Disorder ("MDD"). Beckley Psytech is conducting a Phase 2b controlled study of BPL-003 in patients with TRD, with an anticipated readout in second half of 2024. Initial results from the BPL-003 open-label Phase 2a in TRD were announced in March 2024. Initial results from the BPL-003 open-label Phase 2a study in AUD are anticipated mid-2024. Initial results from the current ELE-01 Phase 1/2a study are anticipated in the first half of 2024. In January 2024, we invested in Beckley Psytech resulting in a 35.5% ownership stake and 1:1 warrant coverage at a 30% premium on the primary issuances. We hold a time-limited right of first refusal on a future sale of the company and an indefinite right of first negotiation for BPL-003 and ELE-101. atai and Beckley Psytech also agreed to collaborate on digital therapeutics, commercial and market access activities in preparation for future potential commercialization. Our interest in the product candidates of Beckley Psytech is limited to the potential appreciation of our equity interest.

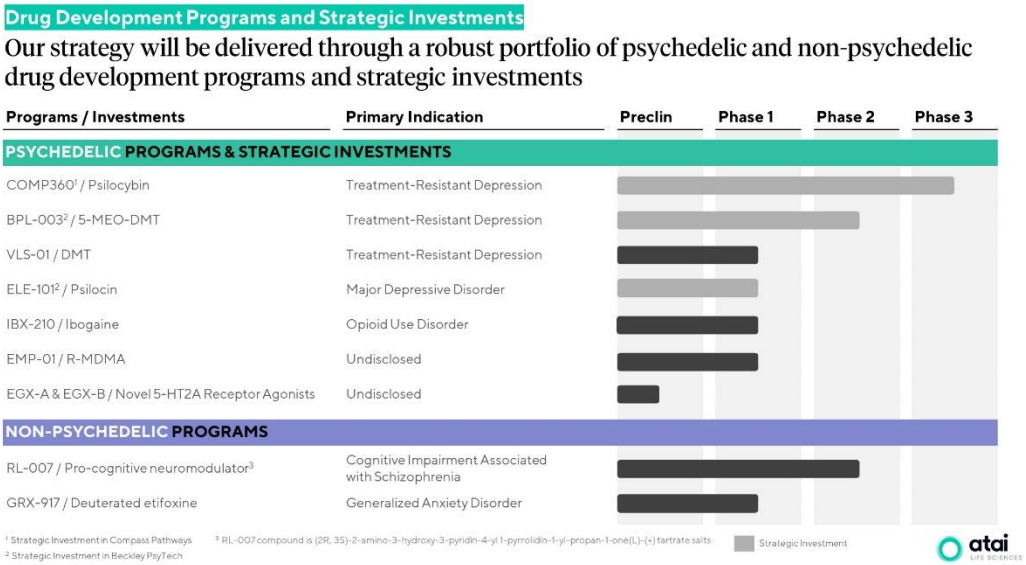
Our Enabling Technologies and Drug Discovery Platforms

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

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

Our Pipeline & Outlook

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



The following details our key psychedelic programs and strategic investments, as well as our non-psychedelic programs, including related prior evidence in humans based on completed and/or on-going clinical trials or studies, recent advancements and upcoming milestones, as applicable:

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

BPL-003 (5-MeO-DMT) for TRD *via Strategic Investment in Beckley Psytech*
BPL-003 is currently being investigated in an on-going Phase 2a open-label study and an on-going Phase 2b double-blind, randomized, controlled study in people living with TRD. In addition, the company is also conducting an open-label Phase 2a study in patients with AUD.

In March 2024, the company announced initial results from Part 1 of the on-going Phase 2a open-label study in patients with moderate to severe TRD. The Phase 2a study investigated the safety, tolerability and efficacy of a single 10mg dose of BPL-003 alongside psychological support in patients who were not taking concomitant antidepressants. 12 subjects were dosed, and 11 met the criteria for per-protocol analysis. Patients were followed for 12 weeks post-dosing, with assessments conducted at multiple points throughout the study. Efficacy was assessed using the Montgomery–Åsberg Depression Rating Scale (MADRS). Initial analysis showed that a single dose of BPL-003 induced a rapid antidepressant response (≥50% reduction in MADRS score) in 55% of patients on the day after dosing. The antidepressant effect was durable, with the 55% response rate maintained at weeks 4and 12. There were 55% of patients in remission (MADRS score ≤10) at week 4 and 45% in remission at week 12.

BPL-003 demonstrated a promising safety profile and was well tolerated. Adverse events (AEs) were predominantly mild or moderate and the most common (>10%) AEs were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings. No serious AEs were reported. The acute effects of BPL-003 resolved on average in less than two hours. These data suggest that BPL-003 could offer a shorter treatment time when compared to other psychedelic treatments currently in development.

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

A randomized, quadruple-masked, controlled Phase 2b study of BPL-003 is currently underway. The study is investigating the effects from a single 12mg or 8mg dose of BPL-003 against a sub-perceptual dose of 0.3mg in 225 patients with TRD. Efficacy will be assessed by masked raters using the MADRS scale at several time points with the primary endpoint at week 4 and final assessment at week 8. Top-line results are expected in H2 2024.

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

VLS-01 (DMT) for TRD
In March 2024, we dosed the first participant in the Phase 1b study of VLS-01. The study is expected to explore doses up to 240 mg with an optimized OTF that incorporates taste masking, an intrinsic backing layer, and enhancements designed to increase permeability with goals of further improving the participant experience and PK. Top-line results are expected in the second half of 2024.

ELE-101 (Psilocin) *via Strategic Investment in Beckley Psytech*
ELE-101 is currently being studied in a two-part Phase 1/2a study. The Phase 1 portion (Part 1) of the study is a randomized, double-blind, placebo-controlled study to assess safety, tolerability, PK and PD of single ascending IV doses of ELE-101 in healthy volunteers. The Phase 2 portion of the study will evaluate a range of PD effects of a single IV dose of ELE-101 in patients with MDD. Initial results from the Phase 1/2a study are anticipated in the first half of 2024.

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

EMP-01: R-3,4-methylenedioxy-methamphetamine ("R-MDMA")
In January 2024, we announced positive top-line results from the Phase 1 study. EMP-01 was well-tolerated, and treatment-related adverse events (AEs) were all expected and generally dose dependent. There were no study discontinuations, and no serious or severe AEs were observed in the study. The PK profile of EMP-01 was dose-proportional. PD measures included both subjective reports and blood-based biomarkers. Significant, consistent, and dose-dependent changes were seen on several of these exploratory PD measures. EMP-01 administration resulted in a differentiated subjective experience compared to racemic MDMA on standard psychedelic experience questionnaires. Further, dose dependent changes on measures of emotional breakthrough, a phenomenon thought to be a key mediator of the long-term psychological changes associated with psychedelics, were noted in this healthy volunteer population. EMP-01 was well-tolerated in all cohorts. We are currently evaluating next steps for the development of EMP-01.

EGX-A and EGX-B (Novel 5-HT2A Receptor Agonists)
As part of atai's drug discovery effort, novel 5-HT2A receptor agonists were discovered that are non-hallucinogenic based on animal studies. The molecules are being further optimized and studied in animal models to assess therapeutic potential.

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

GRX-917 (Deuterated Etifoxine) for Generalized Anxiety Disorder
Following Phase 1 results announced in January 2023, the company is actively looking for partnership and external funding opportunities for this program. The goal is to proceed GRX-917 into a Phase 2 study in patients living with anxiety disorder.

Group structure and corporate reorganization
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. 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.

atai has a two-tier board, consisting of a Supervisory Board and Management Board who are responsible for managing the day-to-day operations as described below.

Financial Overview

We have incurred significant operating losses since our inception. Our net loss attributable to ATAI Life Sciences N.V. stockholders was $43.6 million and $163.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, our accumulated deficit was $565.4 million and $521.2 million, respectively. Our ability to generate product revenue sufficient to achieve profitability will depend substantially on the successful development and eventual commercialization of product candidates at our atai companies that we consolidate based on our controlling financial interest of such entities. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

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

As of December 31, 2023, we had cash and cash equivalents of $45 million and short-term securities of $109.2 million. We believe that our existing cash and cash equivalents and short-term securities will be sufficient for us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following the filing of our Annual Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See ["Liquidity and Capital Resources—Liquidity and Solvency Risks"] below.

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

Financial Summary of the Group	Year ended 31 December 2023 $m	Year ended 31 December 2022 $m
Revenue	0	0
Net loss for the period	(44)	(163)
Net cash used in operating activities	(84)	(104)
Net cash used in investing activities	(53)	(87)
Net cash used in/provided by financing activities	(8)	21

Liquidity and Capital Resources

Sources of Liquidity

Initial Public Offering

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

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

Convertible Promissory Notes

In November 2018, we issued an aggregate principal amount of $0.2 million of convertible notes ("2018 Convertible Notes"). The 2018 Convertible Notes are non-interest-bearing and have a maturity date of September 30, 2025, unless previously redeemed, converted, purchased or cancelled. In October 2020, we issued an additional principal amount of $1.0 million of the 2018 Convertible Notes. Each note has a face value of €1 and is convertible into one ordinary share of ATAI Life Sciences AG upon the payment of €17.00. The noteholders have agreed that, subsequent to converting the notes into ATAI Life Sciences AG share, they will exchange the ATAI Life Sciences AG share for ATAI Life Science N.V. shares.

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

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

As of December 31, 2023 the 2018 Convertible Notes had a principal balance of $0.2 million and the new ATAI Life Sciences N.V. notes had a principal balance of $0.2 million. If all convertible notes were converted, the Company would receive proceeds of €6.6 million (2022: $7.3 million).

Investments
A significant potential source of liquidity resides in our investment in COMPASS's American Depositary shares, subject to market conditions. Based on quoted market prices, the market value of our ownership in COMPASS was $83.7 million as of December 31, 2023. As of December 31, 2023, our ownership percentage in COMPASS was 15.4% (2022: 22.44%).

Hercules Term Loan
On August 9, 2022, we entered into the Loan Agreement with Hercules, which was most recently amended in May 2023. As of December 21, 2023 we had drawn down $15m on the Hercules loan facility (2022: $15m).

Liquidity and Solvency Risks
As of December 31, 2023, we had cash and cash equivalents of $45 million and short-term securities of $109.2 million. We believe that our cash and cash equivalents and short-term securities will be sufficient to fund our projected operating expenses and capital expenditures through at least the next 12 months from the date of our Annual Report.

Our solvency, as determined by dividing the shareholders equity by the total assets, is 0.83 as of December 2023 (2022:0.85).

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

Our future capital requirements will depend on many factors, including:
- the time and cost necessary to complete ongoing and planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities for our ongoing and planned clinical trials, and potential future clinical trials;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third party reimbursement;
- the cash requirements for 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 financing, debt financings, collaborations with other companies and other strategic transactions. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit,

reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

Additional capital requirements

We believe our current cash and cash equivalents position, our expected cash flow generated from operations and our expected financing activities will satisfy our working and other capital requirements for at least the next 12 months based on our current business plans.

Cash flows

The following table summarizes our cash flows for years ended 31 December 2023 and 2022:

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

Cash flow from operating activities

Net cash used in operating activities was $84.1 million for the year ended December 31, 2023, which consisted of a net loss attributable to stockholders of $47.3 million, adjusted by noncash benefit of $44.3 million and net cash inflows from the change in operating assets and liabilities of $7.5 million. The noncash benefit primarily consisted of $86.6 million gain related to the net change in the fair value of our assets and liabilities carried at fair value, $0.5 million of other noncash expenses, and $0.1 million gain on deconsolidation of a subsidiary, partially offset by $33.0 million of stock-based compensation, $3.6 million of losses from our equity method investments, $1.0 million impairment of other investment, $0.8 unrealized foreign exchange losses, and $1.1 million of depreciation and amortization. The net cash inflows from the change in operating assets and liabilities of 7.5 was primarily due to a $8.7 million decrease in prepaid expenses and a $2.1 million increase in accounts payable, partially offset by a $3.3 million decrease in accrued liabilities.

Cash flow from investing activities

Net cash used in investing activities was $53.3 million for the year ended December 31, 2023, primarily driven by $160.3 million of cash paid for securities carried at fair value, $25.0 million of cash committed in anticipation of the closing of Beckley Psytech investment in January 2024, $3.5 million of loans remitted to related party, $2.0 million of cash paid for convertible notes receivable - related party, $1.0 million of cash paid for investments held at fair value, $0.4 million cash paid out in variable interest entity deconsolidation, $0.3 million of cash paid for capitalized internal-use software development costs, and $0.3 million of cash paid for property and equipment, partially offset by $139.0 million of proceeds from sale and maturities of securities at fair value, and $0.5 million of proceeds from sale of other investments.

Cash Flow from Financing activities

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

Human Capital Management

As a company focused on the treatment of mental health concerns, we're dedicated to accelerating patient access to evidence-based innovation in mental health. Our team is the key to our success, and we believe it is essential to invest in building an engaged, diverse, supported, and incentivized workforce who can help us

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

As of December 31, 2023, we had 86 full-time employees and five contractors or consultants doing regular work for the company. Of our full-time employees, 39 focus on driving forward research and development programs (including Digital Therapeutics), either directly or through our subsidiaries. Others provide strategic business development, finance, and executive leadership expertise, as well as operational, communications, legal and administrative services. Approximately two-thirds of our employees are located in the U.S., with the remainder split between the UK and Germany.

In February 2023, we implemented a realignment initiative resulting in a reduction in force of approximately 30% of our global workforce in order to more effectively allocate our research and development and other resources supporting the revised business and program priorities and to reduce operational costs. In February 2024, the Company identified redundancies among certain positions, which resulted in a reduction in force of approximately 10% of the Company's global workforce.

Our four core atai values are: Conscious Care, Bold Entrepreneurship, Collaborative Innovation, and Radical Responsibility. Our human capital philosophy is deeply rooted in these values, which form the core of everything from performance management cycle to hiring decisions.

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

Recruiting

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

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

Professional Development and Performance Management

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

Core Values and Ethics

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

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

All of our managing directors, supervisory directors, officers and employees are responsible for upholding these

values as set forth in our Code of Conduct, which forms the foundation of our policies and practices. The mandatory Code of Conduct is available on our website at https://ir.atai.life/corporate-governance/governance-overview.

Total Rewards and Employee Engagement

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

We invest in the professional development of our employees. All of our employees are strongly encouraged to develop personal development plans with their manager semi-annually in order to define their career goals, and we encourage regular peer and manager feedback. We also offer targeted learning and development opportunities, including team and 1-1 coaching; access to continual growth through online learning platforms; external training where appropriate; and in-house live training, among other opportunities. In addition, to further employee enrichment and engagement, we periodically survey our employees regarding their engagement levels. We use these survey results to determine how we can continue to create work environments that enable and motivate our employees and to develop a positive working culture. We also provide opportunities for our employees to take two working days each year to give back to their communities through volunteerism. 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 successfully 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. In addition, our supervisory directors are comprised of four males and two females as of December 31, 2023.

Hybrid office culture

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

atai Impact

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

Since its inception, atai Impact has announced multiple initiatives, such as the establishment of the atai Fellowship Fund in Psychedelic Neuroscience (the "atai Fellowship Fund") in collaboration with Massachusetts General Hospital's Center for the Neuroscience of Psychedelics. The $2 million atai Fellowship Fund will facilitate further research into the potential of psychedelics to address unmet patient needs in mental health and support promising graduate students in furthering their professional careers in this emerging field.

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 report. 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.

Risk Appetite

Management discusses strategic, finance, operational, compliance and reporting risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. This includes a determination of the risk appetite we have for these risks. Throughout the year, senior management reviews these risks with the supervisory board at regular board meetings as part of management presentations that focus on business functions, operations or strategies, and presents the steps taken by management to control, mitigate or eliminate such risks.

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

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We anticipate that we will incur significant losses for the foreseeable future and have incurred losses in each year since our inception. Our net loss attributable to ATAI Life Sciences N.V. stockholders for the years ended December 31, 2023 and 2022 was $43.6 million and $163.4 million, respectively. We have no products that are approved for commercial sale and have not generated any commercial product revenue. We have financed operations predominantly through the sale of equity securities and debt financings. We continue to incur significant research and development and other expenses related to ongoing operations and building our business infrastructure and expect to incur losses for the foreseeable future.

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

Because of the numerous risks and uncertainties associated with the development of drugs and medical devices, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Authority, or the MHRA, or other comparable foreign regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our existing product candidates and any other product candidates that we may identify. Even if our existing product candidates or any future product candidates that we may identify are

approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product and ongoing compliance efforts.

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

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

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

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

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

As of December 31, 2023, we had $154.2 million in cash and cash equivalents and short-term investment securities. Based on our current operating plan, we estimate that our existing cash, marketable securities and committed term loan funding as of the date this Annual Report will be sufficient to fund operations into 2026. However, our operating plan has, and may continue to change as a result of many factors, some of which may be currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, sales of assets or programs, other sources, such as strategic collaborations or license and development agreements, or a combination of these approaches. We also may opportunistically seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any such additional fundraising efforts for us may divert our management from their day-to-day responsibilities, which may adversely affect our ability to develop and commercialize our product candidates or any future

product candidates we may identify and pursue. Moreover, such financing may result in dilution to shareholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

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

- the time and cost necessary to complete ongoing and planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- the progress, timing, scope and costs of our preclinical studies, clinical trials and other related activities for our ongoing and planned clinical trials, and potential future clinical trials, including progress and related milestones, the failure by third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites, and other circumstances;
- the costs of obtaining clinical and commercial supplies of raw materials and drug products for our product candidates, as applicable, and any other product candidates we may identify and develop;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations, or CMOs;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if approved, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the cash requirements in purchasing additional equity from certain of our atai companies upon the achievement of specified development milestone events;
- the cash requirements of developing our programs and our ability and willingness to finance their continued development;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments, including other products that may compete with one or more of our product candidates;
- the costs of acquiring, licensing or investing in intellectual property rights, products, product candidates and businesses;
- the costs of maintaining, expanding and protecting our intellectual property portfolio;
- our ability to attract, hire and retain qualified personnel as we expand research and development and our operational and commercial infrastructure; and
- the costs of operating as a public company in the United States and maintaining a listing on the Nasdaq Stock Market LLC ("Nasdaq").

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

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

Unless and until we can generate a substantial amount of revenue from our product candidates, we expect our expenses to increase in connection with our planned operations. In order to accomplish our business objectives

and develop our product candidate pipeline, we expect to finance our future cash needs through a combination of public and private equity or debt financings, sales of assets or programs, and other sources, such as strategic collaborations or license and development agreements. Because any decision by us to issue debt or equity securities in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financing transactions. Our board of supervisory directors has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. For example, at December 31, 2023, we had an effective shelf registration statement filed with the SEC in July 2022 registering $300.0 million of securities, of which $150.0 million was reserved for sales under our at-the-market equity offering program, all of which remains available. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for the common shares. We have also filed a registration statement on Form S-8 registering the issuance of common shares issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, certain of our executive officers, employees and affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our common shares. To the extent that we raise additional capital through the sale of equity or convertible debt securities, shareholder ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing shareholders. In addition, the possibility of such issuance may cause the market price of our common shares to decline. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations and liens on our assets, limitations on our ability to acquire, sell or license intellectual property rights, and other operating and financing restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses or other rights on unfavorable terms.

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

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

As part of our strategy, we have and intend to continue to invest in companies that further 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.

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

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

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

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

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

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

A large proportion of our overall value may at any time reside in a small proportion of our atai companies or clinical programs. Accordingly, there is a risk that if one or more of the intellectual property or commercial rights relevant to a valuable business were impaired, this would have a material adverse impact on our overall value. Furthermore, a large proportion of our overall revenue may at any time be the subject of one, or a small number of, licensed technologies. Should the relevant licenses be terminated or expire this would be likely to have a material adverse effect on the revenue received by us.

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

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

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

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

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

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

From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have

a material adverse effect on our business plan, financial condition or operating results and the trading price of our common shares.

Because we have multiple programs and product candidates in our development pipeline, in addition to our continued business development activities, we may, and have in the past decided to, expend our limited resources and allocation of capital to pursue a particular product candidate over other product candidates that may ultimately have been more profitable or for which there may have been a greater likelihood of success, which may adversely affect our future revenues.

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

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

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

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

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

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

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

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

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

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

In addition, clinical trial design for some of our product candidates can be complex given their characteristics. For example, we will need to design clinical trials for certain product candidates to evaluate efficacy across a range of doses. Additionally, we may utilize an “open-label” trial design for some of our future clinical trials. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label studies are aware that they are receiving treatment. Open-label trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Patients selected for early clinical studies often include the most severe sufferers, and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The opportunity for bias in clinical trials as a result of open-label design may not be adequately handled and may cause any of our trials that utilize such design to fail or to be considered inadequate and additional trials may be necessary to support future marketing applications. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or comparable foreign regulatory authorities for support of a marketing application, we may

be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

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

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

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

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

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

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers (with respect to certain of our clinical trials) to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board, or IRB, or ethics committees approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA, or amendment, investigational device exemption, or IDE, or supplement, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments in trials for other product candidates with the same targets or related modalities as our product candidates conducted by competitors that raise regulatory or safety concerns about risk to patients of the treatment, or if the FDA or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulties in securing access to materials for the comparator arm of certain of our clinical trials;
- delays in identifying, recruiting and enrolling suitable patients to participate in clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulties in finding a sufficient number of trial sites, or trial sites deviating from trial protocol or dropping out of a trial;
- difficulty collaborating with patient groups and investigators;
- failure by CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practices requirements, or GCPs, or regulatory guidelines in other countries, including deficiencies in the manufacturing process, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- occurrence of adverse events, or AEs, undesirable side effects or other unexpected characteristics associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of any product candidates that we may identify and pursue being greater than we anticipate;
- clinical trials of any product candidates that we may identify and pursue producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failures by

our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of product candidates that we may identify for use in clinical trials or the inability to do any of the foregoing.

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

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

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

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

Some of our product candidates are regulated by the U.S. Drug Enforcement Administration, or DEA, as "Controlled Substances" or scheduled substances, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, or the CSA. The DEA regulates compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. Commercial marketing in the United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to

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

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

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

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

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

- Importation. If our product candidates are approved and classified as a Schedule II, III or IV substance, an importer can import them for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import

authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration. If our product candidates are approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If our product candidates are listed as a Schedule II substance, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if neither our product candidates nor our drug substances could be imported, the product candidates would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

- Manufacture in the United States. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the active ingredient in our product candidates may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

- Distribution in the United States. If our product candidates are scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our product candidates and any future therapeutic candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our product candidates more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If our product candidates are a Schedule II drug, participants in our supply chain may have to maintain enhanced security with alarms and monitoring systems and they may be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. In addition, our product candidates will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial updates. Furthermore, state and federal enforcement actions, regulatory requirements and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

The EU legislation does not establish different classes of narcotic or psychotropic substances. However, the United Nations, or UN, Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971, or the UN Conventions, codify internationally applicable control measures to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The individual EU member states are all signatories to these UN Conventions. All signatories have a dual obligation to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence. The UN Conventions regulate narcotic drugs and psychotropic substances as Schedule I, II, III, IV substances with Schedule II substances presenting the lowest relative risk of abuse among such substances and Schedule I and IV substances considered to present the highest risk of abuse.

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

comply with the national requirements related to controlled substances which is costly and may affect our development plans in the EU.

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

Our product candidates contain psychedelic substances that may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our current product candidates and any future product candidates we may develop. Opponents of these compounds may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products, if approved. Adverse publicity from misuse may adversely affect the commercial success or market penetration achievable by our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our product candidates or any future therapeutic candidates.

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

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

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

Any product 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, which may reduce the likelihood our product candidates are ultimately approved and therefore may have a material adverse effect on our business and operating results.

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

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

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

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

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

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

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

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, the MHRA or any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the applicable clinical trial was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed

and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA, the MHRA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, the EMA, the MHRA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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

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

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

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

The lengthy approval process, as well as the unpredictability of the results of clinical trials and evolving regulatory requirements, may result in our failure to obtain regulatory approval to market product candidates

that we may pursue in the United States or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

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

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

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

From time to time, we may publicly disclose preliminary or 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.

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

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

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

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

We or our CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our or our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our or our CMOs' manufacturing process could restrict our or their ability to meet potential future market demand for products, if approved.

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

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

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

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

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

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

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

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

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

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the

PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

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

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

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

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

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

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

For any approved product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to

comply with regulatory requirements or experience unanticipated problems with our product candidates, which may adversely impact our financial condition and results of operations.

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

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

Any regulatory approvals that we may receive for our product candidates may contain requirements for potentially costly post-marketing testing, such as Phase 4 clinical trials and surveillance to monitor the safety and efficacy of a drug product. We are required to report certain adverse reactions and production problems, if any, to the FDA, and other comparable foreign regulatory authorities. Any new legislation addressing drug or medical safety issues could result in delays in product development or commercialization or increased costs to assure compliance.

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

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

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

If a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product

or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

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

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

Risks Related to Commercialization

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

To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third

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

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

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

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

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

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

There is significant uncertainty related to the third-party payor coverage and reimbursement of newly approved drugs. The commercial success of our future products in both domestic and international markets depends on whether such third-party coverage and reimbursement is available for our product candidates. Governmental payers, health maintenance organization, managed care, pharmacy benefit and other third-party payers are increasingly attempting to manage their healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate reimbursement for our product candidates, which is essential for most patients to be able to afford treatments. These payers may not view our future products as cost-effective, and coverage and reimbursement may not be available to our customers, may not be sufficient to allow our future products to be marketed on a competitive basis and will

impact our ability to successfully commercialize our product candidates. Government authorities and third-party payers are exerting increasing influence and control on costs, known as cost containment, on their decisions regarding the use of, and coverage and reimbursement levels for, particular medications and treatments. In particular, third-party payers may limit the covered indications. This trend in cost-control initiatives in the United States and other countries could cause us to decrease the price we might establish for products, and monitor and control company profits, which could result in lower than anticipated product revenues. If the prices for our drug candidates decrease or if governmental and other third-party payers do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- Federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements to obtain payment from the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise

restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives.

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

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

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

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

Actual or perceived failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable

health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. We may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, California enacted the California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Further, a new privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA significantly amends the CCPA and will create additional obligations relating to personal information that went into effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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

case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework, or the DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. On October 12, 2023, the UK Extension to the DPF also came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

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

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

In the United States, there have been and continue to be a number of legislative initiatives and judicial challenges to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 percent (effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Payment methodologies may be subject to changes in healthcare legislation and regulatory challenges. For example, in order for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6 percent to ASP minus 22.5 percent on specified covered outpatient drugs, or SCODs, but did so without issuing a formal notice of proposed rulemaking, which was subsequently challenged in court. In June 2022, the U.S. Supreme Court held that although the Department of Health and Human Services, or HHS, has authority to set reimbursement rates based on average price and discretion to "adjust" the price up or down, HHS may not vary the reimbursement rates by hospital group unless it conducts a survey of hospitals' acquisition costs. Accordingly, the U.S. Supreme Court held that HHS's changes to the 2018 and 2019 reimbursement rates for 340B hospitals were unlawful. Based on the foregoing, CMS issued a final rule, effective January 1, 2023, pursuant to which CMS will pay 340B hospitals under Medicare Part B for certain outpatient drugs at the drug's ASP, plus 6%, the same rate used for non-340B hospitals. It is unclear how future changes to the payment methodology may affect pharmaceutical manufacturers and hospitals who purchase their products now and in the future.

There have been a number of significant changes to the ACA and its implementation, as well as judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the

ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, resulted in aggregate reductions of Medicare payments to providers, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

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

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

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

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

from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

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

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

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

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

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

We face competition across our programs in depression, including from Sage Therapeutics, Axsome Therapeutics, GH Research, The Janssen Pharmaceutical Companies of Johnson & Johnson, and Praxis Precision Medicine; CIAS, including from Boehringer Ingelheim, Biogen, Karuna Therapeutics, Minerva Biosciences, Sunovion Pharmaceuticals, and Takeda Pharmaceuticals Vanda and Novartis; SUD, including from BioXcel, Opiant and Intra-Cellular Therapies; anxiety, including from VistaGen Therapeutics, Bionomics and Arvelle Therapeutics; mTBI, including from SanBio, Vasopharm, Levolta Pharmaceuticals, Oxeia, Otsuka and Athersys; as well as in other therapeutic areas and indications.

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

- greater financial, technical, and human resources than we have at every stage of the discovery, development, manufacture, and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing, and selling drug products;

- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disorder indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors may also obtain FDA, or other comparable foreign regulatory approval for their products more rapidly than we may obtain approval for ours or may obtain orphan product exclusivity from the FDA or other comparable foreign authorities for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

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

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

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

Risks Related to Reliance on Third Parties

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

We are currently party to license and collaboration agreements with a number of universities and pharmaceutical companies, and we expect to enter into additional agreements as part of our business strategy. We anticipate relying upon strategic collaborations for marketing and commercializing our existing product candidates, if approved, and we may sell product offerings through strategic partnerships with pharmaceutical

and biotechnology companies. The success of our current and any future collaboration arrangements may depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

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

Management of our relationships with collaborators will require:

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

Additionally, we may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our research and

development efforts and potential to generate revenue may be limited. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license we will achieve an economic benefit that justifies such transaction.

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

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

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

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

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

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under the agreements with such contractors, we cannot control whether or not such contractors devote sufficient time, skill and resources to their ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug or medical device development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain,

or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

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

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

While we currently provide training to the therapists and expect to continue providing trainings in the future (either directly or indirectly through third-party providers), we do not currently employ the therapists who deliver our therapies to patients and do not intend to do so in the future. Such therapists are typically employed by the third-party therapy sites. If any of our current or any future product candidates are approved for commercialization, third-party therapy sites may demand substantial financial resources from us to recruit and retain a team of qualified therapists to administer such products. If the third-party therapy sites fail to recruit, train and retain a sufficient number of therapists, our ability to offer and administer our therapies will be greatly harmed, which may in turn reduce the market acceptance rate of our therapies. If this occurs, our commercialization prospects would be negatively affected and our business, financial condition and results of operations would be harmed.

Although we currently provide training and expect to continue providing training to the therapists (directly or through third-party providers), we generally rely on qualified and certified third-party therapy sites to manage the therapists and monitor the administration of our therapies and ensure that the administration process of our therapies comply with our established protocols. However, if not properly managed and supervised, there is a risk that therapists may deviate from our training protocols, fail to follow the guidelines we have established, or abuse patients during therapeutic administration sessions. The therapists might also administer unauthorized therapies to patients using illegal drug compounds in “underground” clinics. Such illegal activities would put the patients at risk and subject us to potential liabilities, litigation, regulatory proceedings and reputational harm. If this were to occur, we may face serious setbacks for our commercialization process and our financial condition and results of operations would be materially harmed.

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

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture drug supplies for our ongoing clinical trials or any future clinical trials that they may conduct, and we lack the resources to manufacture any product candidates on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers to produce our product candidates or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if any product candidates receive marketing authorization and approval. Although we generally do not begin a clinical trial unless we believe they have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay the clinical development and potential regulatory authorization of our product candidates, which could harm our business and results of operations.

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

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

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

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

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

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for our product candidates, are subject to extensive regulation. Components of a finished drug or product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the United States.

These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed

drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

Obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of much litigation. The standards that the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In some instances, we submit patent applications directly with the USPTO as provisional patent applications. However, U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of the provisional application filing date. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Any pending and future patent applications that we own or in-license may not result in patents being issued that protect our product candidates or technology, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications that we own or license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative product candidates in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges

may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

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

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

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

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

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor

before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

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

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

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

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

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

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

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

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

Our commercial success depends in part on our ability to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to issued patents, and a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. In addition, many companies in the biotechnology and pharmaceutical industries have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our existing product candidates and any other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

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

or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

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

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

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

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments allow a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, such as the Supplementary Protection Certificates in Europe. In particular, a maximum of five and a half years of supplementary protection can be achieved in Europe for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection.

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

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

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

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

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

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

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

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

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

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. If we were to initiate legal proceedings against a third-party to enforce a patent covering one or more of our product candidates, the defendant could allege that we infringe their patents, assert counterclaims that the patent covering our product candidate is invalid and/or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, no obviousness,

written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

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

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property

portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

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

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

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

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

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or other third parties. We may also become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, a court could prohibit us from using technologies or

features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. We may also lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of our owned and licensed patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. However, we cannot guarantee that our licensors have similar systems and procedures in place to pay such fees. In addition, the USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, in EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade

secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been

invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in licensed patent applications and the enforcement or defense of our owned or in licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

Risks Related to Our Business and Industry

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

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

Furthermore, each of our executive officers may terminate their employment with us at any time, subject to notice period requirements. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop,

gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

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

We may need to expand our organization and may experience difficulties in managing this potential growth, which could disrupt our operations.

As we mature, we may need to realign our full-time employee base. This can include expansion or reductions in force, depending on our needs. Our management has diverted, and may need to continue, to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time toward managing these realignment activities. We may not be able to effectively manage a potential realignment of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. For example, in February 2023, we implemented a realignment initiative resulting in a reduction in force of approximately 30% of our global workforce in order to more effectively allocate our research and development and other resources supporting the revised business and program priorities and to reduce operational costs. If our management is unable to effectively manage our internal realignment, our expenses may increase more than expected in the event of an expansion, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future realignment of our employee base.

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

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

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

of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

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

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

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

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

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

We could experience difficulty enforcing our contracts.

Due to the nature of our business and the fact that our contracts involve certain substances whose usage is not legal under U.S. federal law and in certain other jurisdictions, we may face difficulties in enforcing our contracts in U.S. federal and state courts. The inability to enforce any of our contracts could have a material adverse effect on our business, prospects, financial condition and results of operations.

In order to manage our contracts with contractors, we ensure that such contractors are appropriately licensed at the state and federal level in the United States and at the appropriate level in other jurisdictions. Were such contractors to operate outside the terms of these licenses, we may experience an adverse effect on our business, including the pace of development of our product candidates and any future therapeutic candidates.

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

Social media is increasingly being used to communicate about our clinical development programs and the significant number of mental health disorders our 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.

Cyberattacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations which could materially affect our results.

We, our programs, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants rely on information technology, or IT, systems and networks to process, transmit and store electronic information, including but not limited to intellectual property, confidential information, proprietary business information, preclinical and clinical trial data and personal information in connection with our business activities (collectively, "Confidential Information"). Our IT systems and those of current and future third parties on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from cyber incidents, employee error or malfeasance, misconfigurations, "bugs" or other vulnerabilities, theft or misuse, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromises. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g. ransomware), viruses, spamming, social engineering or phishing attacks, denial-of-service attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency, intensity, and sophistication. These threats pose a risk to the security of our, our programs', our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our Confidential Information. There can be no assurance that we will be successful in preventing cyberattacks or successfully mitigating their effects. There can also be no assurance that our, our programs', our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, varying parts of our workforce are currently working remotely on a part or full time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Similarly, there can be no assurance that our

collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any loss of clinical trial data from our completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We have experienced and expect to continue to experience actual and attempted cyberattacks of our IT networks, such as through phishing scams and ransomware. Although we do not believe that we have experienced any significant system failure, accident or cybersecurity incidents to date, we cannot guarantee that we will not experience such incidents in the future. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition.

Any cyberattack that leads to unauthorized access, use, or disclosure of Confidential Information, data breach or destruction or loss of Confidential Information could result in a violation of applicable U.S. and international privacy, data protection and other laws and regulations, require us to notify affected individuals or supervisory authorities, subject us to litigation and governmental investigations, proceedings and regulatory actions by federal, state and local regulatory entities in the United States and by international regulatory entities, cause our exposure to material civil and/or criminal liability and cause us to breach our contractual obligations, which could result in significant legal and financial exposure and reputational damages. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to implement further data protection measures or to remediate any information security vulnerability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage wholly or in part, of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks and the mishandling of data by our employees and third-party service providers, then our business, financial condition, results of operations and prospects could be adversely affected. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

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

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

Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop

critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and comparable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize our company and continue our operations.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

Risks Related to Our International Operations

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

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

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

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

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

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

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

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

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

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

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

Since January 1, 2021, the UK operates under a distinct regulatory regime to the EU. EU pharmaceutical laws only apply in respect of the UK to Northern Ireland (as set out in the Protocol on Ireland/Northern Ireland). EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". The UK Government has proposed to repeal the majority of this retained EU law by the end of 2023 which may lead to further regulatory uncertainty and could result in cost increases for our business. While the UK has indicated a general intention that new laws regarding the development, manufacture and commercialization of medicinal products in the UK will align closely with EU law, there are limited detailed proposals for future regulation of medicinal products. Therefore, there remains political and economic uncertainty regarding to what extent the regulation of medicinal products will differ between the UK and the EU in the future. Any divergences will increase the cost and complexity of running our business, including with respect to the conduct of clinical trials.

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

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global political, regulatory, economic or market conditions and the stability of

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

Risks Related to Our Common Shares

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

Sales of a substantial number of shares of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common shares. This could also impair our ability to raise additional capital through the sale of our equity securities. In addition, the stock market in general has, and will continue to from time to time, experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors have adversely impacted, and may continue to impact, the market price of our common shares, regardless of our operating performance.

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

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

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

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

similarly if investors are precluded from trading their securities, it could have dire consequences on our ability to raise more capital.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, and reduced executive compensation disclosure. We could remain an emerging growth company for up to five years following the initial public offering of our common shares, although circumstances could cause us to lose that status earlier, including if we qualify as a "large accelerated filer," which means the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter, in which case we would no longer be an emerging growth company as of the fiscal year-end.

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

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

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

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

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

Furthermore, we believe that (i) on an unconsolidated basis less than 40% of our total assets (exclusive of U.S. government securities and cash items) are composed of assets that could be considered investment securities, and/or (ii) on a consolidated basis less than 45% of our total assets (exclusive of U.S. government securities and cash items) are composed of, and less than 45% of our income is derived from, assets that could be considered

investment securities. We further believe that we maintain majority control for purposes of Section 3(a)(1)(C) under the Investment Company Act, or primary control for purposes of Rule 3a-1 thereunder, over the majority of the atai companies, and that none of the atai companies over which we have majority or primary control is in the business of investing, reinvesting or trading in securities or otherwise an investment company such that our interests in such atai companies are not considered investment securities for purposes of the Investment Company Act. Accordingly, we do not believe that we are an inadvertent investment company by virtue of the 40% test in Section 3(a)(1)(C) under the Investment Company Act and/or the 45% tests in Rule 3a-1 thereof, as described in the second bullet point above. In addition, we believe that we are not an investment company under Section 3(b)(1) of the Investment Company Act because we are primarily engaged in a non-investment company business.

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

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

We believe that we maintain majority control for purposes of Section 3(a)(1)(C) under the Investment Company Act, or primary control for purposes of Rule 3a-1 thereunder, over the majority of the atai companies, and that none of the atai companies over which we have majority or primary control is in the business of investing, reinvesting or trading in securities or is otherwise an investment company. We monitor and will continue to monitor our holdings in such atai companies in an effort to ensure continuing and ongoing control over such atai companies for purposes of compliance with the requirements of Section 3(a)(1)(C) and/or Rule 3a-1. As a result, we do not believe our interests in such atai companies will be deemed investment securities for purposes of Section 3(a)(1)(C) and/or Rule 3a-1. Accordingly, we believe that (i) on an unconsolidated basis less than 40% of our total assets (exclusive of U.S. government securities and cash items) are composed of assets that could be considered investment securities, and/or (ii) on a consolidated basis less than 45% of our total assets (exclusive of U.S. government securities and cash items) are composed of, and less than 45% of our income is derived from, assets that could be considered investment securities; and we do not believe that we are deemed to be an investment company.

The Investment Company Act and the rules thereunder contain detailed parameters for the organization and operation of investment companies. Among other things, the Investment Company Act and the rules thereunder limit or prohibit transactions with affiliates, impose limitations on the issuance of debt and equity securities, generally prohibit the issuance of options and impose certain governance requirements. We intend to conduct our operations so that we will not be deemed to be an investment company under the Investment Company Act or otherwise conduct our business in a manner that does not subject us to the registration and other requirements of the Investment Company Act. In order to ensure that we are not deemed to be an investment company, we may be limited in the assets that we may continue to own and, further, may need to dispose of or acquire certain assets at such times or on such terms as may be less favorable to us than in the absence of such requirement. If anything were to happen which would cause us to be deemed to be an investment company under the Investment Company Act (such as significant changes in the value of the atai companies or a change

in circumstance that results in a reclassification of our interests in the atai companies for purposes of the Investment Company Act), the requirements imposed by the Investment Company Act could make it impractical for us to continue our business as currently conducted, which would materially adversely affect our business, financial condition and results of operations. In addition, if we were to become inadvertently subject to the Investment Company Act, any violation of the Investment Company Act could subject us to material adverse consequences, including potentially significant regulatory penalties and the possibility that certain of our contracts could be deemed unenforceable.

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

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

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

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

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

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

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

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

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

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

Depending upon the aggregate value and voting power of our common shares that United States persons are treated as owning (directly, indirectly or constructively), we could be treated as a controlled foreign corporation ("CFC"). Additionally, because our group consists of one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as CFCs and lead to adverse U.S. tax consequences for threshold United States holders of common shares, regardless of whether or not we are treated as a CFC. If a United States person (as defined in the United States Internal Revenue Code of 1986, as amended, or the Code) is treated as owning

(directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such person may be treated as a "United States shareholder" with respect to applicable CFCs in our group. Such shareholders are potentially subject to current taxation on their pro rata share of certain CFC income and additional U.S. reporting obligations.

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

Evolving global tax legislation could increase our overall tax burden.

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

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

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

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

to a permanent establishment situated in the Netherlands of a holder that is not (deemed) resident of the Netherlands.

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

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

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

We have net operating losses, or NOLs, in various jurisdictions including Germany and the United States. As of December 31, 2023, our German NOL carryforward was approximately $162.4 million. German tax law imposes certain limits on the utilization of NOLs that are carried forward or carried back to a particular year. Our ability to utilize NOLs may be further limited under Section 8c of the German Corporation Income Tax Act (Körperschaftsteuergesetz – KStG) and Section 10a of the German Trade Tax Act (Gewerbesteuergesetz – GewStG). These additional limitations may apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable.

Generally, a qualified ownership change occurs if more than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding. In the case of such a qualified ownership change, tax loss carryforwards expire in full. To the extent that the tax loss carryforwards do not exceed hidden reserves (stille Reserven) taxable in Germany, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carryforwards will be preserved if certain conditions are satisfied. In case of a qualified ownership change, tax loss carryforwards will be preserved (in the form of a fortführungsgebundener Verlustvortrag) if the business operations have not been changed and will not be changed within the meaning of Section 8d KStG. According to an appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 1 KStG is not in line with the German constitution. In addition, our ability to utilize our NOLs and certain other tax attributes in the United States could be subject to limitation or expire unused under U.S. tax law. As of December 31, 2023, we had U.S. federal NOLs of $52.3 million. In addition, under Section 382 of the United States Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a cumulative change, by value, in our ownership by "5-percent stockholders" that exceeds 50 percentage points over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income or taxes may be limited. If an ownership change occurs and our ability to use our net operating loss carryforward is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

As of December 31, 2023, Apeiron held an 19.7% interest in our Company. Accordingly, Apeiron may, as a practical matter, be able to influence certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances. Such concentration of ownership may also have the effect of delaying or preventing any future proposed change in control. The trading price of our common shares could be adversely affected if potential new investors are disinclined to invest in us because they perceive disadvantages to a large shareholding being concentrated in the hands of a single shareholder. The interests of Apeiron and the investors that acquire our common shares may not be aligned. Apeiron may make acquisitions of, or investments in, other businesses in the same sectors as us or our programs. These businesses may be, or may become, competitors of us or our programs. In addition, other entities managed or advised by Apeiron may be in direct competition with us or our programs on potential acquisitions of, or investments in, certain businesses.

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

We are organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our managing directors, supervisory directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us, our managing directors and supervisory directors and executive officers may be limited under applicable law. In addition, substantially all of our assets are located outside the United States.

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

The United States and the Netherlands do not, as of the date of this filing, have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, it is noted that the Hague Convention on Choice of Court Agreements entered into force for the Netherlands, but has not entered into force for the United States. Accordingly, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to a foreign judgment if (i) the jurisdiction of the foreign court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the foreign court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such foreign judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the foreign court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a foreign judgment is given binding effect, a claim based thereon may, however, still be rejected if the foreign judgment is not or no longer formally enforceable.

In addition, actions brought in a Dutch court against us, our executive officers, directors, senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions or complicating factors. In particular, Dutch courts will apply Dutch private international law

to determine the law applicable to such a claim, which rules may lead to applicability of a different law than U.S. law. Dutch courts do not award punitive or exemplary damages. Litigation in the Netherlands is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Dutch procedural law differs greatly from U.S. law with respect to pre-trial discovery and the disclosure of evidence during trial. Proceedings in the Netherlands would, in principle, have to be conducted in the Dutch language. For these reasons, it may be difficult for a U.S. investor to bring an original action in a Dutch court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our executive officers, directors and senior management. Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our managing directors, supervisory directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

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

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

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

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

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

The rights of shareholders and the responsibilities of managing directors and supervisory directors may be different from the rights and obligations of shareholders and directors in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our managing directors and supervisory directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible

that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

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

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

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

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

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

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

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

We do not comply with all best practice provisions of the Dutch Corporate Governance Code, or DCGC.

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

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

As a public company, we are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for each Annual Report on Form 10-K we file with the SEC. This assessment includes disclosure of any material weaknesses identified by our management in internal control over financial reporting. In the future, when we

are no longer an emerging growth company, our independent registered public accounting firm will also be required to attest to the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K to be filed with the SEC pursuant to Section 404(b) of the Sarbanes-Oxley Act. We are also required to disclose material changes made in our internal control over financial reporting on a quarterly basis. Failure to comply with the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC, the stock exchange on which our securities are listed or other regulatory authorities, which would require additional financial and management resources. Compliance with Section 404 requires that we incur substantial costs and expend significant management efforts.

We have previously disclosed a material weakness in our internal control over financial reporting in our consolidated financial statements for the fiscal year ended December 31, 2021. While management has concluded that the previously identified material weaknesses in internal control over financial reporting were remediated as of December 31, 2022, we can give no assurance that additional material weaknesses will not be identified in the future. We continue to implement measures designed to improve our internal controls over financial reporting A material weakness in our internal control over financial reporting could result in an increased probability of fraud, litigation from our shareholders, reduction in our ability to obtain financing, and require additional expenditures to remediate. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in loss of investor confidence in the accuracy and completeness of our financial reports and a decline in our share price, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

General Risk Factors

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

We may engage in various additional acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

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

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

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

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

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

Moreover, persistent economic downturns may require us to undertake optimization and cost saving initiatives, including streamlining our organization and adjusting the size and structure of our workforce. For example, throughout 2022 and 2023, we implemented certain cost reduction efforts to reduce material spend and operating expenses. In February 2023, we restructured our workforce and eliminated approximately 30% of our global workforce in order to more effectively allocate our research and development and other resources to support the revised business and program priorities and to reduce operational costs. Any reduction in force may yield unintended consequences and costs, such as attrition beyond the intended reduction in force, the distraction of employees and reduced employee morale, which could, in turn, adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge or inefficiency during transitional periods. Any of these impacts could also adversely affect our reputation as an employer, make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the restructuring.

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

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

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

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

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

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, trial sites, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

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

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

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

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

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social, and governance and other sustainability matters, such as climate change and diversity, equity, and inclusion. We may experience pressure to make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social, and governance matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

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

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

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

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, increased carbon disclosure and transparency, and upgrade of facilities to meet new building codes, which could increase our operating costs. Our supply chain would likely be subject to these same transitional risks and would likely pass along increased costs to us.

Corporate Governance

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

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

- Engaged consultants to assist management in designing and implementing a formal risk assessment process.
- Formalized our accounting and financial reporting policies and the related procedures and designed and implemented controls over the timely recording, review, and reconciliation of financial transactions, including expense and stock-based compensation transactions.
- Hired additional qualified accounting personnel and implemented accounting systems to support our

policies, procedures and controls, while maintaining segregation of duties amongst accounting personnel.

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

Management has completed its documentation, testing and evaluation of the enhanced controls and determined that, as of December 31, 2023, our controls have been appropriately designed and implemented, and have operated effectively for a sufficient period of time to conclude that these previously identified material weaknesses have been remediated.

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 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-recognised stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with the following best practice provisions of the DCGC:

Independence of supervisory board members and Independence of the chairman of the supervisory board:

All of our supervisory directors, other than Christian Angermayer, qualify as "independent" in accordance with Nasdaq listing requirements. The Nasdaq independence definition includes a series of objective tests, including that the supervisory director is not, and has not been for at least three years, one of our employees and that neither the supervisory director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our supervisory board has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our supervisory board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a supervisory director. In making these determinations, our supervisory board reviewed and discussed information provided by the supervisory directors and us with regard to each supervisory director's business and personal activities and relationships as they may relate to us and our management. For details of the related party transaction, please see note 8.11 of the consolidated financial statements.

Related Party Transaction Policy

Our supervisory board adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. Under the policy, our legal team is primarily responsible for developing and implementing processes and procedures to obtain information regarding related persons with respect to potential related person transactions and then determining, based on the facts and circumstances, whether such potential related person transactions do, in fact, constitute related person transactions requiring compliance with our policy. A related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which the Company and any related person are, were or will be participants in which the amount involved exceeds $120,000. Pursuant to the policy, transactions involving (i) compensation to an executive officer, member of the management board or member of the supervisory board, if such compensation is required to be reported in our proxy statement and has been approved by the supervisory board or remuneration committee of the supervisory board, (ii) compensation for services provided to the Company as an executive officer who is not an immediate family member of a related person if the executive officer was a named executive officer in the proxy statement and such remuneration has been approved, or recommended to the supervisory board for approval, by the compensation committee of the supervisory board, and (iii) certain ordinary course of business transactions have been pre-approved by the audit committee. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities and any of their respective immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our general counsel must present information regarding the related person transaction to the audit committee, for review, consideration and approval or ratification. The presentation must include a description of, among other things, all relevant facts and

circumstances relating thereto. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related- person transactions and to effectuate the terms of the policy. In considering related person transactions, our audit committee will take into account the relevant available facts and circumstances including, but not limited to:

- whether the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party; and
- the extent of the related person's interest in the transaction and the conflicts of interest and corporate opportunity provisions of the Company's Code of Conduct.

Mr. Angermayer was determined not to be independent because he is the founder of Apeiron Investment Group Ltd., one of our principal shareholders.

Attendance at Supervisory Board Meetings:

There were five meetings of the supervisory board during fiscal year 2023. In accordance with applicable SEC requirements, during fiscal year 2023, each incumbent director attended at least 75% of the aggregate of (i) all meetings of the supervisory board and (ii) all meetings of the committees on which the director served during the period in which he or she served as a director. In addition, with respect to our Annual General Meeting, all of our then-incumbent directors attended our annual meeting of shareholders held in 2023.

In determining whether to recommend a supervisory director for re-appointment, our nominating committee may also consider a director's past attendance at meetings and participation in and contributions to the activities of the supervisory board. However, we and the supervisory board also recognize that there may be instances when a director is unable to attend a meeting due to various personal and/or professional conflicts.

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.

The reason for the above statement is that we believe that in substance, we do comply with the material and relevant to our company parts of the DCGC, by means of our Form 10-K as filed with the SEC. This filing contains, including but not limited to, the following sections:

i. internal control over financial reporting;
ii. Functioning of the relevant management and supervisory bodies and committees;
iii. Information about corporate governance;
iv. Information about our diversity policy.

In accordance with the relevant Dutch decree about the management board report, i.e. 'Besluit inhoud bestuursverslag' the Corporate Governance information can be made public via electronic means. As indicated in the section 'Introduction', all our SEC filings are permanently available via our corporate website.

Cancelling the binding nature of a nomination or dismissal

The members of our management board and supervisory board are appointed, or re-appointed as the case may be, by the Company's general meeting (the "General Meeting") of shareholders in accordance with the Articles of Association to serve until their successors are duly elected and qualified or until their term of appointment lapses.

The General Meeting may only 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.
Similarly, our articles of association provide that a resolution of the General Meeting to suspend or dismiss a (managing or supervisory) director, other than pursuant to and in accordance with a proposal by the supervisory board, will require a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital.

In control statement

Based on the approach described above, the Executive Board is of the opinion that, to the best of its knowledge:

- the Report of the Management Board provides sufficient insights into any failings in the effectiveness

of the risk management and internal control systems;
- the Company has designed and implemented an internal control framework, based on the principles of SOX;
- the Company have outsourced their internal audit function to test the effectiveness of controls within the internal control framework;
- the risk management and internal control systems provide reasonable assurance that the financial reporting, including tax, does not contain any material inaccuracies;
- based on the current state of affairs, it is justified that the financial reporting is prepared on a going concern basis; and
- the Report of the Management Board states those material risks and uncertainties that are relevant to the expectation of atai continuity for the period of twelve months after the date of the Report of the Management Board.

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

Properly designed and implemented risk management and internal control systems significantly reduce, but cannot fully eliminate, the possibility of human errors, poor judgement, deliberate circumvention of controls, fraud or infringements of laws, rules or regulations, or the occurrence of unforeseeable circumstances. Another factor considered within risk management is that efforts related to risk management and internal control systems should be balanced against the costs of implementation and maintenance.

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.

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 SEC.

Share Capital
As of December 31, 2023, 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.

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 Chief Executive Officer 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).

Code of conduct and other corporate governance practices
The Company has adopted a written code of business conduct and ethics (the "Code of Conduct") that applies to our supervisory directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and others temporarily assigned to perform work or services to atai. The text of the Company's Code of Conduct can be accessed via our website, www.atai.life and atai intends to post on its website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the Code of Conduct.

The Code of Conduct operated effectively during the year to which the Management Board Report pertains.

General meeting

Functioning of the General Meeting
Annually, according to Dutch law at least one annual general meeting of the Company must be held. Unless extended applying applicable rules of Dutch law, this annual general meeting must be held within six months after the end of the Company's fiscal year.

A General Meeting must also be held within three months after the management board has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital.

In addition, without prejudice to the relevant best practice provisions of the DCGC with respect to invoking a

'response period', a General Meeting must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met.

Any additional General Meeting shall be convened whenever the management board or the supervisory board so decide.

Each General Meeting must be held in the place included in our articles of association.

For purposes of determining who has voting rights and/or meeting rights under Dutch law at a General Meeting, the management board may set a record date, which must be the 28th day prior to the date of the General Meeting.

Those who have voting rights and/or meeting rights under Dutch law as of the record date and are recorded as such in one or more registers designated by the management board shall be considered to have those rights at the General Meeting, irrespective of any changes in the composition of the shareholder base between the record date and the date of the General Meeting.

The Company's articles of association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend the General Meeting. Such notice must be received by the Company ultimately on the seventh day prior to the General Meeting, unless indicated otherwise when such General Meeting is convened.

Powers of the General Meeting
All powers that do not vest in the management board or the supervisory board pursuant to applicable law, the Company's articles of association or otherwise, vest in the Company's General Meeting.

The main powers of the General Meeting include, subject in each case to the applicable provisions in the Company's articles of association:

- the appointment, suspension and dismissal of managing directors and supervisory directors, upon a binding nomination by the supervisory board;
- the approval of certain resolutions of the management board concerning a material change to the identity or the character of the Company or its business;
- the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of shares in its capital;
- adoption of the Company's statutory annual accounts;
- the appointment of the Dutch independent auditor to examine the Company's statutory annual accounts;
- amendments to the Company's articles of association;
- approving a merger or demerger by the Company, without prejudice to the authority of the management board to resolve on certain types of mergers and demergers if certain requirements are met; and
- the dissolution of the Company.

In addition, the General Meeting has the right to, and the management board and the supervisory board must provide, any information reasonably requested by the General Meeting, unless this would be contrary to an overriding interest of the Company.

Shareholder rights
Each share in the Company's capital carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address the General Meeting, subject to the said concept of a record date). In the amendment of our articles of association effected as per 1 July 2022, we included that subject to any provision of mandatory Dutch law and any higher quorum requirement stipulated in our articles of association, if and for as long as the Company is subject to the rules and requirements of a securities exchange and such securities exchange requires the Company to have a quorum for

the general meeting of shareholders, then the general meeting of shareholders can only pass resolutions if at least one third of our issued and outstanding shares are present or represented at such general meeting.

Furthermore, each share in the Company's capital carries an entitlement to dividends and other distributions as set forth in the Company's articles of association. Pursuant to the Company's articles of association, any such dividend or other distribution shall be payable on such date as determined by the management board and the management board may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base).

The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced.

In addition, shareholders have those rights awarded to them by applicable law.

Management board
The management board is charged with managing the Company's affairs and the implementation of its strategy. In performing their duties, the managing directors shall be guided by the interests of the Company and of the business connected with it.

The management board has developed a view on long-term value creation by the Company and has formulated a strategy consistent with that view.

The supervisory board has been actively engaged in formulating the Company's strategy and supervises the manner in which the strategy is implemented.

Supervisory board
The supervisory board is charged with the oversight of the management board and the general course of affairs of the Company and of the business connected with it. The supervisory board provides the management board with advice. In performing their duties, the supervisory directors shall be guided by the interests of the Company and of the business connected with it.

The management board provides the supervisory board with the information necessary for the performance of its tasks in a timely fashion. At least once a year, the management board also informs the supervisory board in writing of the main features of the strategic policy, the general and financial risks and the administration and control system of the Company.

All of our supervisory board members, other than Christian Angermayer, are independent under best practice provision 2.1.8 paragraphs i. through vii. of the DCGC. Mr. Angermayer is not independent because he is the founder of Apeiron Investment Group Ltd., one of our principal shareholders.

Anti-takeover measures
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

Committees

General

The supervisory board has established an audit committee, a compensation committee and a nominating committee. Each committee operates pursuant to its written charter, each of which has been approved by the supervisory board and is available on the Company's website at https://ir.atai.life/corporate-governance/governance-overview.

The following table depicts the composition of the committees:

		Committees		
Supervisory Board	**Position**	**Audit**	**Compensation**	**Nominating**
Christian Angermayer	Chair	-	-	-
Michael Auerbach	Lead Independent Director	-	Member	-
Jason Camm	Director	-	-	-
Sabrina Martucci Johnson	Director	Chair	-	Chair
Amir Kalali, M.D.	Director	Member	-	Member
Andrea Heslin Smiley	Director	Member	Chair	Member

Audit committee

The responsibilities of the audit committee include the following:

- Appointment and Oversight. The Committee is directly responsible for the appointment, compensation, retention and oversight of the work of the independent auditor (including resolution of any disagreements between Company management and the independent auditor regarding financial reporting) and any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or related work or performing other audit, review or attestation services for the Company, and the independent auditor and each such other registered public accounting firm must report directly to the Committee. The Committee, the Chair of the Committee or a Committee member to whom pre-approval authority has been delegated must pre-approve any audit and non-audit service provided to the Company by the independent auditor, unless the engagement is entered into pursuant to appropriate preapproval policies established by the Committee or if such service falls within available exceptions under SEC rules;
- Report on Independence. The Committee must ensure that the independent auditor prepares and delivers, at least annually, a written statement delineating all relationships between the independent auditor and the Company, must actively engage in a dialogue with the independent auditor with respect to any disclosed relationships or services that, in the view of the Committee, may impact the objectivity

and independence of the independent auditor, and, if the Committee determines that further inquiry is advisable, must take appropriate action in response to the independent auditor's report to satisfy itself of the auditor's independence;

- Annual Audited Financial Statements. The Committee must review and discuss the annual audited financial statements with management and the independent auditor, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations.";
- Audit Committee Report. The Committee must provide the Company with the report of the Committee with respect to the audited financial statements for inclusion in each of the Company's annual proxy statements;
- Review of Earnings Releases. The Committee must discuss the Company's earnings press releases, as well as financial information and earnings guidance provided to analysts and rating agencies;
- Risk Assessment and Risk Management. The Committee must discuss the Company's policies with respect to risk assessment and risk management, including guidelines and policies to govern the process by which the Company's exposure to risk is handled, and oversee management of the Company's enterprise risk, including financial and cybersecurity risks;
- Litigation and Regulatory Compliance. The Committee must review, with the General Counsel and outside legal counsel, legal and regulatory matters, including legal cases against or regulatory investigations of the Company and its subsidiaries, that could have a significant impact on the Company's financial statements;
- Complaint Procedures. The Committee must establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and for the confidential and anonymous submission by Company employees of concerns regarding questionable accounting or auditing matters;
- Review of Related Party Transactions. The Committee must review all related person transactions as defined by Item 404 of Regulation S-K on an ongoing basis and all such transactions must be approved by the Committee. The Committee shall review and discuss with the Company's independent auditor any matters required to be discussed by applicable auditing standards, including with respect to related party transactions;
- Reports to the supervisory board. The Committee must report regularly to the Supervisory Board regarding the activities, deliberations and findings of the Committee, including as required under applicable Dutch laws and regulations;
- Committee Self-Evaluation. The Committee must at least annually perform an evaluation of the performance of the Committee;
- Review of its Charter. The Committee must annually review and reassess its Charter and submit any recommended changes to the Supervisory Board for its consideration;
- Review of Code of Conduct. The Committee must, at least annually, consider and discuss with management and the independent auditor the Company's Code of Conduct and the procedures in place to enforce the Code of Conduct. The Committee must also consider and discuss and, as appropriate, grant requested waivers from the Code of Conduct brought to the attention of the Committee, though the Committee may defer any decision with respect to any waiver to the Supervisory Board.

Compensation committee

The responsibilities of the compensation committee include:

- Executive Officer Compensation. The Committee shall review and recommend for approval by the supervisory board the compensation of the Company's Chief Executive Officer (the "CEO") and the Company's other executive officers, including members of the management board, including salary, bonus and incentive compensation levels; deferred compensation; executive perquisites; equity compensation (including awards to induce employment); severance arrangements; change-in-control benefits; and other forms of executive officer compensation. The Committee shall meet without the presence of executive officers when approving or deliberating on CEO compensation but may, in its discretion, invite the CEO to be present during the approval of, or deliberations with respect to, other executive officer compensation.
- Director Compensation. The Committee will periodically review and make recommendations to the supervisory board regarding Managing Director and Supervisory Director compensation.

- Compensation Committee Report. The Committee will prepare the annual Compensation Committee Report, to the extent required under applicable rules and regulations of the U.S. Securities and Exchange Commission.
- Reports to the supervisory board. The Committee must report regularly to the supervisory board regarding the activities of the Committee.
- Incentive Compensation and Equity-Based Plans. The Committee will review and approve or make recommendations to the supervisory board regarding the Company's incentive compensation and equity-based plans and arrangements.
- Employment Agreements and Severance Plans. The Committee will review and make recommendations to the supervisory board regarding employment agreements and severance arrangements or plans for the Chief Executive Officer and the Company's other executive officers.
- Regulatory Compliance. The Committee will review regulatory compliance with respect to compensation matters, including ensuring that reasonable efforts are made to structure compensation programs to preserve tax deductibility.
- Compensation Discussion and Analysis. To the extent that the Company is required to include a "Compensation Discussion and Analysis" ("CD&A") in the Report or annual proxy statement, the Committee will review and discuss with management the Company's CD&A and will consider whether it will recommend to the Supervisory Board that the Company's CD&A be included in the appropriate filing.
- Committee Self-Evaluation. The Committee will periodically perform an evaluation of its performance.
- Review of its Charter. The Committee must annually review and reassess its Charter and submit any recommended changes to the Supervisory Directors for its consideration.

Nominating committee
The duties and responsibilities of the nominating committee include:

- Director Nominees. The Committee will identify individuals qualified to become members of the supervisory board and the management board and ensure that the supervisory board and the management board have the requisite mix of diverse backgrounds and expertise. The Committee will also recommend to the supervisory board the nominees for election to the supervisory board and the management board at the next annual meeting of shareholders;
- Criteria for Selecting Members for Nomination. The criteria to be used by the Committee in recommending members of the supervisory board and/or management board are as set forth in the Company's Rules of the Board of Supervisory Directors and Rules of the Board of Managing Directors, respectively;
- Supervisory Board Committee Structure and Membership. The Committee will annually review the supervisory board committee structure and recommend to the supervisory board for its approval directors to serve as members of each committee of the supervisory board. Corporate Governance and Additional Duties;
- Corporate Governance Guidelines. The Committee will develop and recommend to the supervisory board the Corporate Governance Guidelines for the supervisory board. The Committee will, from time to time as it deems appropriate, review and reassess the adequacy of such corporate governance guidelines and recommend any proposed changes to the supervisory board for approval. The Committee may recommend to the management board amendments to the Corporate Governance Guidelines for the management board. The Committee will, from time to time as it deems appropriate, review and reassess the adequacy of such corporate governance guidelines and recommend any proposed changes to the management board, subject to approval by the supervisory board;
- Supervisory board and management evaluations. The Committee will oversee the annual self-evaluations of the supervisory board, the management board and management;
- Other Corporate Governance Matters. The Committee may make recommendations to the supervisory board regarding governance matters, including, but not limited to, the Company's Articles, corporate governance guidelines and the charters of the Company's other committees;
- Reports to the supervisory board. The Committee must report regularly to the supervisory board regarding the activities of the Committee;
- Committee Self-Evaluation. The Committee shall annually perform an evaluation of its performance.

- Review of its Charter. The Committee must annually review and reassess its Charter and submit any recommended changes to the supervisory board for its consideration.

Evaluation
During the fiscal year to which this Report relates, the supervisory board has evaluated its own performance, the performance of the committees of the supervisory board and that of the individual managing directors and supervisory directors.

As part of this evaluation process, the supervisory board has considered:
(i) substantive aspects, mutual interaction and the interaction between the supervisory board and the management board;
(ii) events that occurred in practice from which lessons may be learned; and
(iii) the desired profile, composition, competencies and expertise of the supervisory board.

In addition, the management board has evaluated its own functioning and that of the individual managing directors. These evaluations are intended to facilitate an examination and discussion by the management board and the supervisory board of their effectiveness and areas for improvement. On the basis of these evaluations, the supervisory board has concluded that the management board and the supervisory board are functioning properly.

Diversity
In evaluating the suitability of individual candidates (both new candidates and current supervisory board members), the nominating committee, in recommending candidates for appointment, and the supervisory board, in approving (and, in the case of vacancies, appointing), may take into account many factors, including: personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; strong finance experience; experience relevant to our industry; experience as a board member or executive officer of another publicly held company; experience relevant to an international company; relevant academic expertise or other proficiency in an area of our operations; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; diversity of background and perspective, including, but not limited to, with respect to age, gender, ethnicity and specialized experience; practical and mature business judgment, including, but not limited to, the ability to make independent analytical inquiries; and any other relevant qualifications, attributes or skills. The supervisory board evaluates each individual in the context of the supervisory board, with the objective of assembling a group that can best perpetuate the long-term success and sustainability of the business and further the interests of our stakeholders, including shareholders, through the exercise of sound judgment using its diversity of experience in these various areas.

In line with best practice provision 2.1.5 of the Dutch Corporate Governance Code, the Supervisory Board has adopted the diversity policy (the "Diversity Policy") for the composition of the Supervisory Board, the Management Board and key leadership positions. This Diversity Policy addresses (a) the diversity aspects relevant to the Company, (b) the specific objectives set out in relation to diversity, and (c) the implementation of the Diversity Policy. The Company have been successful in achieving their target of 33% women at the board level while also implementing targets and metrics to track further results of the Diversity Policy.

These diversity aspects shall be considered when composing the Supervisory Board and the Management Board and selecting their members.

As of December 31, 2023 the company had 33% women at the Supervisory Board level, 16% women at the Management Board level and 23% women at the internal management level (SVP/VP). Other than as required by applicable law, the Company doesn't have a documented target ratio. However, pursuant to its Supervisory Board Corporate Governance Guidelines, in recommending candidates for appointment to the Supervisory Board, the Company's Nominating and Governance Committee and Supervisory Board take into account several factors, including diversity of background and perspective, including, but not limited to, age, gender and ethnicity. For future appointments of members of these boards, the Company will continue to consider the

appropriate diversity and experience of potential candidates, including with respect to gender, and endeavor to achieve a preferred balance of [approximately] 33% women.

The following specific diversity objectives have been identified to promote the diversity within the Supervisory Board and the Management Board:

(iv) nationality, age and gender diversity within the supervisory board; and
(v) nationality, age and gender diversity within the management board.

The Company aims to have a minimum of one-third women and a minimum of one-third men on the supervisory board. However, when nominating a candidate for appointment, the qualifications of the candidate, as well as the requirements for the positions to be filled, shall prevail.

In order to meet the diversity objectives, the said diversity aspects are considered and taken into account by atai for recruitment, appointment to roles, succession planning, training and development.

The Supervisory Board shall review the Diversity Policy and the implementation regularly. The Supervisory Board shall update the Diversity Policy if and when necessary.

Herein and in the company's corporate governance statement, the Diversity Policy and the way it has been implemented in practice shall be explained, addressing more specifically: (i) the objectives of the Diversity Policy, (ii) how the Diversity Policy has been implemented, and (iii) the results of the Diversity Policy in the past financial year.

Below is an outline of the current state of affairs, along with an explanation as to which measures are being taken to attain the intended objectives, and by when this is likely to be achieved.

If the composition of the Management Board and the Supervisory Board diverges from the objectives stipulated in the Diversity Policy, and to the extent this is provided under or pursuant to Dutch law, the Company's corporate governance statement shall include an outline of the current state of affairs, along with an explanation as to which measures are being taken to attain the intended objectives, and by when this is likely to be achieved.

The Company continues to strive to meet its objectives under its Diversity Policy and will continue to do so when appointing new members to its management board and supervisory board.

Board Diversity Matrix

Country of Principal Executive Offices	Germany			
Foreign Private Issuer	No			
Disclosure Prohibited Under Home Country Law	No			
Total Number of Directors	6			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	2	4	—	—
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	—	1	—	—
LGBTQ+	—	1	—	—
Did Not Disclose Demographic Background	—	—	—	—

Remuneration
The existing renumeration policy of the Company (the "Renumeration Policy") for the management board was adopted prior to and in view of atai's IPO.

The Remuneration Policy is designed to attract and retain highly qualified individuals, incentivize performance and shareholder value creation, and align compensation with performance.

If and when the Renumeration Policy is revised, the aspects referred to in the best practice provisions of chapter 3 of the DCGC shall be considered. However, our long-term incentive plan does allow the Company to grant equity awards that are not subject to a lock-up period of at least five years after the date of grant, and without restricting the exercisability of equity awards during the three years after the date of grant.

For a detailed description of the implementation of our remuneration policy and the rules promulgated thereunder and as recommended by the DCGC, see *Officers Renumeration* in 8.8 notes to the consolidated financial statements.

Remuneration of directors.
The remuneration of the supervisory board members is not solely cash based and part of the reward for members of the supervisory board may be paid in the form of shares, options and/or other securities.

See *Remuneration of the Board of Directors* included in 8.9 notes to the consolidated financial statements.

Supervisory Board Report

The members of the supervisory board wish to thank all atai employees and the members of the management board for the progress made during 2023 toward achieving atai's strategic goals.

We would also like to thank our shareholders, customers, business partners and other stakeholders for their continued collaboration and confidence in atai.

The supervisory board is committed to increasing shareholder value as the members represent the interests of all stakeholders, including shareholders. atai is committed to a corporate governance structure that best suits its business and stakeholders and complies with relevant rules and regulations.

atai is subject to the Dutch Corporate Governance Code as last amended on December 8, 2016. Our policy is to follow the guidelines as set forth in the Dutch Corporate Governance Code, although some deviations may result from the impact of factors such as legal requirements imposed on atai as an entity with common shares listed on the Nasdaq Stock Market LLC ("Nasdaq") and registered with the U.S. Securities and Exchange Commission and/or industry standards. Therefore, atai is also subject to the corporate governance rules set forth under applicable U.S. laws and Nasdaq.

atai's common shares are listed and traded in the U.S. on Nasdaq. For a more detailed description on corporate governance please refer to the proxy statement attached for reference purposes (Annex) (the "Proxy Statement")).

Our supervisory board oversees the management board and the general course of affairs of atai. The supervisory board gives advice to the management board and is guided by the interests of the business when performing its duties.

The management board communicates regularly with the supervisory board.

Members of the supervisory board are appointed by shareholders at a general meeting upon a binding nomination of the supervisory board. The nominating committee of the supervisory board recommends members for nomination to the supervisory board. The members of the supervisory board are not authorized to represent atai in dealings with third parties.

The supervisory board held five meetings during fiscal year 2023.

During fiscal year 2023, each director had 100% attendance to the meetings of the supervisory board and meetings of the committees on which the supervisory director served during the period in which he or she served as a supervisory director.

The supervisory board performs evaluations related to the functioning of the supervisory board, its committees, the individual members and the chairpersons of the supervisory board and its committees, as well as the functioning of the management board and its individual members and the composition and competence of both boards.

Composition of the management board and the supervisory board

atai's management board is composed of its chief executive officer and its chief financial officer, both of whom are male. atai's supervisory board is composed of six members, two of whom are female. atai continues its aim to populate the supervisory board in accordance with the composition profile as adopted by the supervisory board. Moreover, atai believes that the members of its supervisory board have a broad range of experiences, expertise and backgrounds, and that the backgrounds and qualifications of the supervisory board members, considered as a group, provide a significant mix of experience, knowledge, abilities and independence that we believe will allow our supervisory board to fulfill its responsibilities and properly execute its duties.

atai regularly reviews the composition of its management and supervisory boards to ensure such boards have the right mix of experience, qualifications and diversity. In the future, the Company does not rule out appointing females to achieve a balanced distribution of seats. Our supervisory board is comprised of six members and

in accordance with the composition profile as adopted by the supervisory board. A supervisory board member may be appointed for a limited time and any member may be re-appointed. However, the Corporate Governance Guidelines – Supervisory Board of atai provide that a person may be appointed as supervisory director for a maximum of two consecutive terms of up to four years and, subsequently, for a maximum of two consecutive terms of up to two years each.

Pursuant to the Rules of the Board of Supervisory Directors, our supervisory board members do not have a retirement age requirement under our Articles of Association. Our supervisory board members are elected, or re-appointed as the case may be, by our general meeting of shareholders in accordance with the Articles of Association to serve until their successors are duly elected and qualified or until their term of appointment lapses.

Currently, certain members of our supervisory board are not independent within the means of the Dutch Corporate Governance Code. Specifically, our Chairman, as he is a representative of (and/or employed by) a shareholder.

For further details and biographies of the members of the supervisory board, we refer to the Proxy Statement.

Committees of the supervisory board
The supervisory board has established an audit committee, a compensation committee, and a nominating committee, each of which operates pursuant to a written charter adopted by the supervisory board. The charters of each of the supervisory board's committees are available on the Company's website at https://ir.atai.life/corporate-governance/governance-overview.

Financial statements and audits
The Dutch statutory financial statements for fiscal year 2023 are presented as prepared by the management board and audited by Deloitte Accountants B.V. The supervisory board has reviewed the financial statements and the management board report.

The supervisory board has no objections and concurs with the results of the audit. All Supervisory Directors will co-sign the Annual Report.

Regards,

/s/ Christian Angermayer

Christian Angermayer (Chairman)

Corporate Governance Statement

This statement is included pursuant to Section 2(a) of the Decree on the Content of the Directors' Report (Besluit inhoud bestuursverslag) and will also be made available in digital form on the Corporate Governance page of the Company's website.

The information that must be included in this statement pursuant to Sections 3, 3(a), and 3(b) of said decree can be found in the following sections of the Management Board report.

The sections referred to below should be regarded as included and repeated here:

- information on compliance with the principles and best-practice provisions of the 2016 Corporate Governance Code (above, 'Corporate Governance');
- information on the functioning of the General Meeting of Shareholders and its principal powers, and on the rights of shareholders and how these can be exercised (above 'General Meeting');
- information on the composition and performance of the management board (above 'Management Board');
- information on the composition and performance of the supervisory board and its committees (above, 'Supervisory board' 'Committees');
- policy on diversity in inter alia the composition of the Management and Supervisory Boards ('Diversity');
- the company's capital structure, and the associated rights and obligations (See the financial statements);
- every limitation imposed by the company on the transfer of shares issued with the company's cooperation (above, 'General Meeting');
- every limitation on voting rights and deadlines for exercising voting rights (above 'General Meeting');
- the rules and regulations regarding appointment and dismissal of Management Board members and Supervisory Board members and changes to the articles of association (Schedule 3 – paragraph 1.6 'Powers of the General Meeting');
- information on the principal features of the management and control system in connection with the Group's financial reporting process, as follows:

Signature page to the board report of atai Life Sciences N.V. for the fiscal year ended December 31, 2023.

Signature	Title	Date
/s/ Florian Brand Florian Brand	Chief Executive Officer and Managing Director (Principal Executive Officer)	April 22, 2024
/s/ Anne Johnson Anne Johnson	Chief Financial Officer (Principal Financial Officer)	April 22, 2024
/s/ Christian Angermayer Christian Angermayer	Chairman of the Supervisory Board	April 22, 2024
/s/ Michael Auerbach Michael Auerbach	Supervisory Director	April 22, 2024
/s/ Jason Camm Jason Camm	Supervisory Director	April 22, 2024
/s/ Sabrina Martucci Johnson Sabrina Martucci Johnson	Supervisory Director	April 22, 2024
/s/ Amir Kalali Amir Kalali	Supervisory Director	April 22, 2024
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Supervisory Director	April 22, 2024

ATAI Life Sciences N.V.

Consolidated Financial Statements

As of December 31, 2023

CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Statements of Profit & loss and Other Comprehensive Income (Loss)

Consolidated Statements of Profit & Loss

(In USD thousands, except per share amounts)	Notes		
		2023	**2022**
Revenue	**5.1**	314	233
Research and development expenses	**5.2**	(63.202)	(76.490)
Acquisition of in-process research and development	**5.3**	-	(357)
General Administrative Expenses	**5.4**	(65.948)	(79.225)
Operating Loss		**(128.836)**	**(155.839)**
Finance Income (expense)	**5.7**	953	7.450
Other Income (expense)	**5.8**	85.172	671
Profit on the disposal of subsidiary	**5.9**	60	1.484
Net loss before income taxes		**(42.651)**	**(146.234)**
Benefit from (provision for) income taxes	**5.10**	(1.016)	(6.229)
Share of loss of associates and joint ventures accounted for using the equity method	**5.11**	(3.593)	(16.006)
Net loss for the period		**(47.260)**	**(168.469)**
Net loss for the period			
Net loss is attributable to:			
Noncontrolling interests	**5.12**	(3.671)	(5.032)
atai Life Sciences N.V. stockholders		(43.589)	(163.437)
Net loss per share attributable to atai Life Sciences N.V. stockholders – basic and diluted		**(0.27)**	**(1.05)**
Weighted average common shares outstanding attributable to atai Life Sciences N.V. stockholders – basic and diluted		158.833.785	155.719.585

Consolidated Statements of Profit & loss and Other Comprehensive Income (Loss)

Other Comprehensive Income (Loss)

	Notes	2023	2022
Loss for the Period		**(47.260)**	**(168.469)**
Other Comprehensive Income (loss):			
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:			
Foreign currency translation adjustments, net of tax		2.242	(13.366)
Total comprehensive income (loss) for the year		**(45.018)**	**(181.835)**
Comprehensive income attributable to noncontrolling interests		(3.671)	(5.032)
Foreign currency translation adjustments, net of tax attributable to noncontrolling interests		(1)	50
Comprehensive income (loss) attributable to atai Life Sciences N.V. stockholders		(41.346)	(176.853)
Total comprehensive income (loss)		**(45.018)**	**(181.835)**

Consolidated Statements of Financial Position

(In USD thousands, except per share amounts)	Notes	12.31.2023	12.31.2022
Assets			
Non-Current Assets			
Property and equipment, net		981	928
Equity method investments	**6.1**	1.838	5.387
Other investments	**6.2**	83.700	1.368
Financial fixed assets	**6.3**	6,125	-
Long term notes receivable- related parties		97	7.262
Convertible notes receivable - related party	**6.4**	11.202	-
Other assets	**6.5**	3.943	3.351
Total non-current assets		**107.886**	**18.296**
Current assets			
Cash and cash equivalents	**6.6**	45.034	190.613
Securities held at fair value	**6.7**	109.223	82.496
Funds held in trust	**6.8**	25.000	-
Prepaid expenses and other current assets	**6.9**	5.830	14.036
Short term notes receivable		505	-
Total current assets		**185.592**	**287.145**
Total assets		**293.478**	**305.441**
Equity and liabilities			
Liabilities			
Non-current liabilities:			
Non-current portion of contingent consideration liability – related parties	**6.10**	620	953
Non-current portion of contingent consideration liability	**6.11**	1.637	-
Convertible promissory notes -related parties, net of discounts and deferred issuance costs		164	415
Convertible promissory notes	**6.12**	2.666	-
Long-term debt	**6.13**	15.047	14.702
Other liabilities	**6.14**	8.908	3.708
Total non-current liabilities		**29.042**	**19.778**
Current liabilities:			
Accounts payable	**6.14**	4.589	2.399
Accrued liabilities	**6.15**	15.256	17.306
Other current liabilities		275	192
Total current liabilities		**20.120**	**19.897**
Total liabilities		**49.162**	**39.675**
Equity			
Share Capital		18.573	18.562
Share premium		809.204	785.144
Share subscription receivable		-	(24)
Accumulated other comprehensive income (loss)		(19.460)	(21.702)
Accumulated Deficit		(565.355)	(521.240)
Total stockholders' equity attributable to atai Life Sciences N.V. shareholders		**242.962**	**260.740**
Noncontrolling interests	**2.2**	1.354	5.026
Total Stockholders' equity		**244.316**	**265.766**
Total liabilities and stockholders' equity		**293.478**	**305.441**

Consolidated Statements of Changes in Equity

(In USD thousands, except per share amounts)	Notes	Common Shares	Share capital	Share premium	Share Subscriptions Receivables	Accumulated other Comprehensive income (loss)	Accumulated Deficit	Total Stockholders' Equity attributable to atai Life Sciences N.V. Stockholders	Noncontrolling interests	Total Stockholders' Equity
Balance as of 1 Jan 2022		**160.677.001**	**18.002**	**725.045**	**-**	**(8.336)**	**(357.803)**	**376.908**	**9.052**	**385.960**
Net loss:			-	-		-	**(163.437)**	**(163.437)**	(5.032)	**(168.469)**
Conversion of convertible notes to common stock	**8.1**	4.320.000	447	4.466		-	-	4.913	-	**4.913**
Issuance of shares upon exercise of stock options		938.913	113	2.206	(24)	-	-	2.295	-	**2.295**
Issuance of subsidiary preferred shares		-	-	-		-	-	-	600	**600**
Issuance of subsidiary common shares		-	-	-		-	-	-	357	**357**
Stock-based compensation expense		-	-	53.427		-	-	53.427	-	**53.427**
Foreign currency translation adjustment, net of tax		-	-	-		(13.366)	-	(13.366)	50	**(13.317)**
Balance as of 31 Dec 2022		**165.935.914**	**18.562**	**785.144**	**(24)**	**(21.702)**	**(521.240)**	**260.740**	**5.026**	**265.766**

Consolidated Statements of Changes in Equity

(In USD thousands, except per share amounts)		Common Shares	Share Capital	Share Premium	Accumulated Deficit	Share Subscriptions Receivables	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity attributable to atai Life Sciences N.V. Stockholders	Non-controlling interests	Total Equity
Balance as of 1 Jan 20223	**Notes**	**165.935.914**	**18.562**	**785.144**	**(521.240**)	**(24)**	**(21.702)**	**260.740**	**5.026**	**265.766**
Net loss:			-	-	(43.589)	-	-	(43.589)	(3.671)	**(47.260)**
Issuance of shares upon note conversion	**8.1**									
	8.1	15.920	2	18	-	-	-	20	-	**20**
Issuance of shares upon exercise of stock options	**8.1**	74.562	9	172	-	-	-	181	-	**181**
Settlement of issuance of shares upon exercise of stock options		-	-	-	-	24	-	24	-	**24**
Adjustment to additional paid in capital upon consolidation and deconsolidation	**8.2**	-	-	(10.809)	-	-	-	(10.809)	-	**(10.809)**
Adjustment to additional paid in capital upon debt modification			-	(1.668)	-	-	-	(1.668)	-	**(1.668)**
Adjustment to accumulated deficit (IFRS 9 - ECLs)		-	-	-	(526)	-	-	(526)	-	**(526)**
Stock-based compensation expense		-	-	36.347	-	-	-	36.347	-	**36.347**
Foreign currency translation adjustment, net of tax			-	-	-	-	2.242	2.242	(1)	**2.241**
Balance at Dec 31, 2023		**166.026.396**	**18.573**	809.204	**(565.355)**	**-**	**(19.460)**	**242.962**	**1.354**	**244.316**

Consolidated Statements of Cash Flows

(In USD thousands, except per share amounts)	Notes	12.31.2023	12.31.2022
Cash Flows from operating Activities	**7**		
Net Loss		(**47.260**)	**(168.469)**
Adjustments for:			
Depreciation and amortization expense		319	168
Noncash lease expense		383	-
Amortization of debt discount		371	131
Acquired in-process research and development expense	**5.3**	-	357
Stock-based compensation expense		36.347	53.427
Change in fair value measurement		(86.583)	(2.083)
Impairment of other investments		1.011	-
Gain on deconsolidation of subsidiary	**5.9**	(60)	(1.484)
Impairment of loan receivable		-	852
Provision for deferred income taxes		-	5.074
Unrealized foreign exchange gains		799	(4.950)
Losses from investments in equity method investees		3.593	16.006
Other		(507)	(161)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		8.663	(1.522)
Accounts payable		2.138	(3.034)
Accrued liabilities		(3.332)	1.221
Net cash used in operating activities		**(84.118)**	**(104.467)**
Cash Flows from investing activities	**7**		
Cash paid for securities carried at fair value		(160.262)	(309.058)
Proceeds from sale and maturities of securities carried at fair value		138.983	226.834
Funds transferred to trust		(25.000)	-
Purchases of property and equipment		(259)	(773)
Capitalized internal-use software development costs		(331)	(251)
Cash paid for other investments held at fair value		(956)	-
Cash paid for other investments		-	(600)
Proceeds from sale of other investments		486	-
Loans to related parties		(3.500)	(3.000)
Cash paid for convertible notes receivable - related party		(2.014)	-
Cash paid out in variable interest entity deconsolidation		(443)	-
Net cash used in investing activities	**7**	**(53.295)**	**(86.848)**
Cash Flows from financing activities	**7**		
Proceeds from issuance of subsidiary preferred shares		-	600
Cash paid for acquisition of noncontrolling interest		(8.480)	
Exercise of stock options		205	2.294
Proceeds from conversion of convertible notes to common stock		20	4.636
Proceeds from debt financings		-	15.000
Financing costs paid		(100)	(1.745)
Net cash provided by financing activities	**7**	**(8.355)**	**20.785**
Effect of foreign exchange rate changes on cash		189	(1.123)
Net increase (decrease in cash and cash equivalent)		(145.578)	(171.653)
Cash and cash equivalents – beginning of the period	**6.5**	190.613	362.266
Cash and cash equivalents- end of the period		**45.034**	**190.613**

See also note 7 to the financial statements

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Corporate Information

atai Life Sciences N.V 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.

atai has its registered office and its actual place of business at Wallstraße 16, 10179 Berlin, Germany. Its statutory seat is in Amsterdam, Netherlands, and the company is registered in the Trade Register at the Chamber of Commerce under number CoC 80299776.

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

These financial statements were authorised for issue by the Board of Directors on April 22, 2024.

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 7 February 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, including offering costs deferred in 2020 amounting to approximately $1.6 million.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. As of December 31, 2023, the Company had cash and cash equivalents of $45.0 million, short-term securities of $109.2 million and its accumulated deficit was $565.4million. The Company has historically financed its operations through the sale of equity securities, debt financings, sale of convertible notes and revenue generated from licensing and collaboration arrangements. The Company has not generated any revenues to date from the sale of its product candidates and does not anticipate generating any revenues from the sale of its product candidates unless and until it successfully completes development and obtains regulatory approval to market its product candidates.

The Company currently expects that its existing cash and cash equivalents as of December 31, 2023 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 Preparation and Summary of Significant Accounting Policies

The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

2.1 Basis of preparation

Statement of compliance

The Company prepared its consolidated financial statements in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRSs) and with Section 2:362(9) of the Dutch Civil Code as part of the statutory financial statements filing. Except as otherwise noted, the Company has consistently applied the accounting policies to all periods presented in these consolidated financial statements.

New and amended standards adopted by the Group

The following amendments have been adopted effective January 1, 2023 and do not have a material impact on the consolidated financial statements of the Group:

- Disclosure of Accounting Policies (Amendment to IAS 1 and IFRS Practice Statement 2)
- Definition of Accounting Estimates (Amendment to IAS 8)

New standard not yet adopted

The following standards issued will be adopted in a future period and the potential impact, if any, they will have on the Group's consolidated financial statements is being assessed:

- Lease Liability in a Sale and Leaseback (Amendment to IFRS 16)

- Classification of Liabilities as Current or Non-Current (Amendment to IAS 1)
- Amendment – Non-current Liabilities with Covenants (Amendment to IAS 1)
- Presentation and Disclosures in Financial Statements (Amendment to IFRS 18)
- Insurance Contracts (Amendment to IFRS 17)

Basis of accounting and fair value measurement

The consolidated financial statements have been prepared on a historical cost basis, except for derivative financial instruments, debt and equity financial assets and contingent consideration that have been measured at fair value.
The Group measures financial instruments such as derivatives, notes receivable and certain equity investments at fair value at each balance sheet date.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

- In the principal market for the asset or liability

Or

- In the absence of a principal market, in the most advantageous market for the asset or liability

The principal or the most advantageous market must be accessible by the Group.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

1. Level 1 : Quoted (unadjusted) market prices in active markets for identical assets or liabilities.
2. Level 2 : Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.
3. Level 3 : Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The preparation of consolidated financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires the Board of Directors to exercise its judgement in the process of applying atai's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in Note 3.

Except for certain contingent consideration liability (refer to note 6.7), there are no significant non-current liabilities valued at fair value, which impact the financial position and performance of the group. Furthermore, there are no movements between fair value hierarchy levels. If relevant, additional information is disclosed in the notes to the financial statements.

Foreign Currency
The Group's consolidated financial statements are presented in US Dollars ("USD"), which is also the parent company's functional currency. Unless otherwise stated, the numbers are rounded to thousands of USD, except per share amounts.

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 recognised as a component of other income (expense), net in the consolidated statements of changes in equity.

Current and non-current classification
The Group presents assets and liabilities in the statement of financial position based on current/non-current classification.

Current assets include assets that are sold, consumed or realized as part of the normal operating cycle (operating cycle is assumed to be 12 months), or cash and cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.

Current liabilities, such as trade payables, lease liabilities or employee benefits with a term of up to 12 months, and payables for operating costs or social security charges, are part of the working capital used in the Group's normal operating cycle. Such operating items are classified as current liabilities even if they are due to be settled more than 12 months after the reporting period. All other liabilities are classified as non-current.

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

2.2 Basis of consolidation

The consolidated financial statements include the accounts of atai Life Sciences N.V. and all subsidiaries that are controlled by the Company. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. All intercompany balances and transactions have been eliminated in the consolidated financial statements. The non-controlling interests are disclosed separately in the consolidated statement of profit & loss and statement of comprehensive income as part of profit allocation and in the consolidated balance sheet as a separate component of equity.

The directors have, at the time of approving the financial statements, a reasonable expectation that the Group have adequate resources to continue in operational existence for the foreseeable future. Thus they continue to adopt the going concern basis of accounting in preparing the financial statements.

The fiscal year of all Group entities corresponds to the calendar year ending December 31, 2023. Consolidated 100% companies:

Name	Registered Office	Share in issued share capital
atai Life Sciences US Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
atai Life Sciences AG*	Wallstraße 16, 10179 Berlin, Germany	100%
atai Life Sciences UK Ltd.	One Fleet Place London EC4M 7WS United Kingdom	100%
atai Life Sciences Australia Pty Ltd	Level 7, 330 Collins Street, Melbourne, 3000, Australia	100%
Atai Therapeutics Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
Atai Therapeutics Australia Pty Ltd*	Level 7, 330 Collins Street, Melbourne, 3000, Australia	100%
DemeRX IB, Inc*	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
EntheogeniX Biosciences, Inc*	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
IntroSpect Digital Therapeutics Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
InnarisBio, Inc*	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
InnarisBio Australia Pty Ltd*	Level 7, 330 Collins Street, Melbourne, 3000, Australia	100%
EmpathBio Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
EmpathBio Australia Pty Ltd*	Level 7, 330 Collins Street, Melbourne, 3000, Australia	100%
Revixia Life Sciences Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%
Revixia Life Sciences Australia Pty Ltd*	Level 7, 330 Collins Street, Melbourne, 3000, Australia	100%
Invyxis Inc.	c/o Industrious NYC, 250 West 34th Street, New York, NY 10119	100%

*AG sits directly below NV and is the main operating entity holding all of the subsidiaries noted above. Additionally, the Australian entities noted above are subsidiaries of their respective US parent (i.e. Atai Therapeutics Australia Pty Ltd is subsidiary of Atai Therapeutics Inc.)

Consolidated non-wholly owned subsidiaries:

Name	Registered Office	2023 % held	2022 % held
Perception Neuroscience Holdings, Inc	524 Broadway, 11th Floor, New York, NY 10012, United States	59.2%	58.9%
Kures, Inc	1477 Paseo De Las Flores Encinitas, CA 92024, United States	64.48%	64.48%
Kures Australia Pty Ltd	58 Gipps Street Collingwood VIC 3066 Australia	64.48%	64.48%
DemeRX IB, Inc*	3542 Waterfront Dr Gainesville, GA 30506	100%	59.5%
EntheogeniX Biosciences, Inc*	1477 Paseo De Las Flores Encinitas, CA 92024, United States	100%	80.0%
Recognify Life Sciences, Inc	1000 Marina Blvd, Suite 105 Brisbane, CA 94005	51.9%	51.9%
Psyber, Inc**	1040 W. Adams Street, Unit 416 Chicago, IL 60607	0%	75.0%
PsyProtix, Inc	524 Broadway, 11th Floor, New York, NY 10012, United States	75.0%	75.0%
InnarisBio, Inc*	524 Broadway, 11th Floor, New York, NY 10012, United States	100%	82.0%
InnarisBio Australia Pty Ltd*	58 Gipps Street Collingwood VIC 3066 Australia	100%	82.0%
TryptageniX, Inc**	524 Broadway, 11th Floor, New York, NY 10012, United States	0%	65.0%

* DemeRX IB, Inc, EntheogeniX Biosciences, Inc, InnarisBio, Inc and InnarisBio Australia Pty Ltd non-controlling interest was purchased during 2023 creating wholly owned subsidiaries.
**Psyber, Inc and TryptageniX, Inc were deconsolidated in 2023

For all of the above subsidiaries, non-controlling interests are retained by the founders and / or key management personnel of the investees. As of December 31, 2023 and December 31, 2022, the assets of the consolidated entities can only be used to settle the obligations of the respective entity. The liabilities of the consolidated entities are obligations of the respective entity, and their creditors have no recourse to the general credit or assets of atai.

The results of operations of the consolidated entities are included within the Company's consolidated financial statements from the date of acquisition to December 31, 2023.

The amount of net loss attributable to noncontrolling interests are included in the consolidated net loss on the face of the consolidated statements of profit & loss. All subsidiaries' primary activities are related to the developing and / or commercializing innovative technologies and medication for mental health disorder treatments. Except for Perception, none of the subsidiaries have revenue.

2.3 Summary of material policies

Asset Acquisitions and Business combinations
The Company evaluates each of its acquisitions under the IFRS 3 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 an optional concentration test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquired set is a business. During the years ended December 31, 2022, 2021 and 2020, the Company did not have any acquisitions that were accounted for as business combinations. As a consequence, no goodwill was recognised.

Acquisition-related expenses incurred by the Company in asset acquisitions 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. Also acquired in-process research and development ("IPR&D") with no economic useful life / no alternative future use does not satisfy the criteria for recognition as an intangible asset and accordingly assessed for impairment and expensed as research and development expense at the acquisition date. It is worth noting that IPR&D charge-off relates to the impairment of acquired IPR&D cost in an asset acquisition and is treated differently than the internally generated R&D expenses.

Equity-accounted investments
The Company applies the equity method to account for investments when it possesses the ability to exercise significant influence, but not control, over the operating and financial decisions of the investee. Generally, the ability to exercise significant influence is presumed when the investor possesses more than 20% of the voting interests of the investee. This presumption may be overcome based on specific facts and circumstances that demonstrate that the ability to exercise significant influence is not present. The Company applies the equity method to investments in common stock and to other investments in nonconsolidated entities that have risk and reward characteristics that are substantially similar to an investment in the investee's common stock.

In applying the equity method, the Company's investments are initially recorded at cost 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 amortises basis differences identified on a straight-line basis over the underlying assets estimated useful lives when calculating the attributable earnings or losses. 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 recognise 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 profit & loss. 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 recognised 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 impairment at each reporting period. atai tests an investment for impairment by comparing its recoverable amount (the higher of its value in use or its fair value less costs to sell) with its carrying amount, whenever there is an indication for impairment. Note that for the years ending December 31, 2021, 2022 and 2023 there were no objective evidence that suggested impairment occurred after initial recognition. 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 profit & loss. 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, reversals of impairment and any impairment related to equity method investments as losses from investments in equity method investees on the consolidated statement of profit & loss. The Company did not identify factors that would indicate that a potential other-than-temporary impairment of the carrying values of its equity method investments had occurred during the years ended December 31, 2022, 2021 and 2020.

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 at fair value , by means of the initial cost less

impairment losses as a proxy to fair value, 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 recognise related to these investments are presented as a component of other income (expense), net in the consolidated statements of profit & loss.
The Company performs a qualitative assessment at each reporting period considering impairment indicators to evaluate whether the investment is impaired. Impairment indicators that the Company considers include but are not limited to; i) a significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee, ii) a significant adverse change in the regulatory, economic, or technological environment of the investee, iii) a significant adverse change in the general market condition of either the geographical area or the industry in which the investee operates, iv) a bona fide offer to purchase, an offer by the investee to sell, or a completed auction process for the same or similar investment for an amount less than the carrying amount of that investment; v) factors that raise significant concerns about the investee's ability to continue as a going concern, such as negative cash flows from operations, working capital deficiencies, or noncompliance with statutory capital requirements or debt covenants. If the qualitative assessment indicates that an investment is impaired, a loss is recorded equal to the difference between the fair value and carrying value of the investment.

Convertible Notes Receivable
The Company has elected the fair value option to account for its IntelGenx convertible notes. In accordance with IFRS 9, the Company records this investment at fair value under Convertible notes receivable – related party in the Company's consolidated balance sheets and changes in fair value are recognized as Change in fair value measurement, a component of other income(expense), net in the consolidated statements of profit & loss.

Notes Receivable
The Company has certain notes receivable that are carried at amortised cost, which includes the principal value of the note receivable, accrued interest and net of any payments received and impairment losses recognise. In accordance with IFRS 9, the Group applies the expected credit loss (ECL) model for the measurement and recognition of impairment loss on financial assets measured at amortised cost e.g., notes receivable and bank balances. As of December 31, 2023, there is no impairment loss recognized associated with the notes receivable that are carried at cost. Based on the terms of the notes receivable, certain notes receivable are classified as long term as their payments are due after twelve months from the balance sheet date.

Cash and Cash Equivalents
The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2023 and December 31, 2022, cash and cash equivalents consisted of cash on deposit and cash held in high-yield savings accounts and money market funds which is at free disposal to the company.

Contingent Consideration Liability—Related Parties
The Company may record contingent consideration as part of the cost of acquisitions. Contingent consideration is recognised 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 fulfilment of the contingency. Changes in the fair value of the contingent consideration are recognise as a component of other income (expense), net in the consolidated statements of operations.

Share-based payment awards
The Group operates a number of share-based payment programs.

An equity-settled share-based payment award is accounted for by recognizing the related expense over the vesting period of the award, with corresponding increase recorded in equity. The expense is based on the fair value determined at the grant date of the award and the number of awards expected to vest. The fair value remains unchanged after grant date. If there is no final grant date due to terms that have yet to be implemented, the fair value is based on an estimated grant date. Once the award has vested, there is no reversal of expense related to the award.

When a share-based payment award provides for different ways of settlement (i.e. cash versus shares) depending on the occurrence of contingent events, the award is accounted for based on the manner of settlement that is most probable. A change in the expected manner of settlement is accounted for as a modification.

Expenses for employer taxes arising upon the exercise of equity-settled share-based payments are recognise in profit or loss.
The related share-based payment expense is recorded in the functional cost category to which the award recipient's costs are classified

Revenue recognition
The Group primarily generates revenue from its licensing and development agreements with collaboration partners for the development of against a variety of targets in diseases and conditions. These arrangements contain multiple contractual promises, including:

- licenses, or options to obtain licenses, to the Group's technology,
- delivery of products and
- research and development services.

Such arrangements provide for various types of payments to the Group, including upfront fees, funding of research and development services, payment for delivered products, development, regulatory and commercial milestone payments, license fees and royalties on product sales, all of which may be satisfied at different points in time.

A receivable is recognised when the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant contractually agreed pricing in force at the date of customer placing the respective order for such goods or services. Amounts received prior to satisfying the above revenue recognition criteria are recorded as contract liability in the statements of financial position.

Research and Development Costs
atai's (internal) research and development programs are in various stages of progression. The technical or commercial viability of the programs has not been established yet, however. As a result, research and development costs are treated and accounted as research costs and 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. Non-refundable 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.

Noncontrolling Interests
The Company recognises noncontrolling interests related to its consolidated subsidiaries 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 subsidiary that do not result in a loss of control are accounted for as equity transactions. The noncontrolling interests related to its consolidated subsidiaries are initially recorded at fair value. Net losses in consolidated subsidiaries are attributed to noncontrolling interests considering the liquidation preferences of the different classes of equity held by the shareholders in the subsidiary and their respective interests in the net assets of the consolidated subsidiary 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. NCI represents residual economic interest and meets the requirement for classification as equity under IFRS 10.

NCI shares are redeemable upon occurrence of deemed liquidation events (e.g., change of control, sale of the company etc.), as well as upon successful completion of phase 2 of clinical development process. However, the

Company notes that it controls both contingencies because the occurrence of deemed liquidation event or the successful completion of phase 2 require its approval. To fulfil its fiduciary responsibilities, the Company and the Board continuously assesses the developmental progress across the platform, prioritizes or de-prioritizes the allocation of limited resources amongst the competing candidates to ensure only compounds with highest potential are advanced to next phase (e.g., Phase 2 or Phase 2A). Therefore, the Company concluded that the contingencies which could trigger redemption is not beyond its control and notes no contractual obligation exists that meets the requirement of financial liability at inception.

The amount of net loss attributable to noncontrolling interests are included in consolidated net loss on the face of the consolidated statements of profit & loss.

Taxes

Current income tax
Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognised directly in equity is recognised in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax
Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

1. When the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.
2. In respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised, except:

3. When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.
4. In respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, deferred tax assets are recognised only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available, against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognised outside profit or loss is recognised outside profit or loss. Deferred tax items are recognised in correlation to the underlying transaction either in OCI or directly in equity.

Tax benefits acquired as part of a business combination, but not satisfying the criteria for separate recognition at that date, are recognised subsequently if new information about facts and circumstances change. The adjustment is either treated as a reduction in goodwill (as long as it does not exceed goodwill) if it was incurred during the measurement period or recognised in profit or loss.

The Group offsets deferred tax assets and deferred tax liabilities if and only if it has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and /assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

3. Significant accounting judgments, estimates and assumptions

In preparing the consolidated financial statements, management has made judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income, and expenses. Actual results may differ from these estimates.

Management continually evaluates its judgments and estimates in relation to assets, liabilities, contingent liabilities, revenues, and expenses. Management bases its judgments and estimates on historical experience and on other various factors, it believes to be reasonable under the circumstances, the result of which forms the basis of the carrying values of assets and liabilities that are not readily apparent from other sources.

Judgments

In the process of applying the accounting policies, atai has made several judgements, which have an effect on the amounts recognised in the consolidated financial statements. The most significant judgments are stated below.

Consolidation

atai holds the majority equity interest in Gaba Therapeutics, Inc ('GABA'). The board of directors ("Board") of GABA controls and directs all key operating and financing decisions in the Company and atai does not control the Board which is controlled by the minority shareholders. Hence, it is determined that atai does not control GABA and accordingly, does not consolidated GABA. Investment in GABA is accounted for under the equity method investment.

Asset Acquisitions vs. Business Combinations

All acquisitions are evaluated under IFRS 3 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 performs the optional concentration test (also referred to as 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. In our assessments we conclude the concentration tests are met for the acquisitions we made during 2022.

In identifying the individual assets and liabilities, we assess whether the acquired in-process research and development ("IPR&D") assets have economic useful life or alternative future use. If it does not satisfy the criteria for recognition as an intangible asset under IFRS and it is assessed for impairment and expensed as research and development expense at the acquisition date.

Evaluating the reasonableness of these estimations and the assumptions and inputs used in making determination requires a significant amount of judgement and is therefore subject to an inherent risk of error

Estimates
Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

Actual results may differ from these estimates under different assumptions and conditions and may materially affect the financial results or the financial position reported in future periods. Information about assumptions and estimation uncertainties that may have a significant risk of resulting in a material adjustment is included below.

Equity method investments
At each reporting date, the Company assesses whether there is an indication that an asset may be impaired. If there is any indication of impairment or if an annual impairment test is required, the Company estimates the recoverable amount of the asset. The recoverable amount of an asset is the higher of the asset's fair value less costs of disposal and its value-in-use.

We assessed whether objective indicators of impairment exist based on the "loss event" criteria in IAS 28. We considered, among other things, the indications of significant financial difficulty of the investee, significant adverse changes in the technological, market, economic or legal environment in which the investee operates and significant or prolonged decline in the fair value of an investment in an equity instrument below its cost, if any, as objective evidence of impairment and note that currently there are no equity method investments with objective indicators supporting these investments as impaired.

Research and Development Expenses
Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates. We expense research and development costs as incurred. Research expenditures are reflected in the income statement. Development expenses are currently also reflected in the income statement because the criteria for capitalization are not met.

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. Non-refundable 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. Although we do not expect the estimates to be materially different from amounts actually incurred, the understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in reporting amounts that are too high or too low in any particular period.

Convertible debt
The terms of our convertible debt agreements are evaluated to determine whether the convertible debt instruments contain both liability and equity components, in which case the instrument is a compound financial instrument. Convertible debt agreements are also evaluated to determine whether they contain embedded derivatives, in which case the instrument is a hybrid financial instrument. Judgement is required to determine the classification of such financial instruments based on the terms and conditions of the convertible debt agreements, the currencies in which the debt instruments are denominated and the Company's functional currency.

Estimation methods are used to determine the fair values of the liability and equity components of compound financial instruments and to determine the fair value of embedded derivatives included in hybrid financial instruments. The determination of the effective interest used for the host contracts of hybrid financial instruments and the liability components of compound financial instruments is dependent on the outcome of such estimations. Evaluating the reasonableness of these estimations and the assumptions and inputs used in the valuation methods requires a significant amount of judgement and is therefore subject to an inherent risk of error.

Going concern
Continuation of an entity as a going concern is presumed as the basis for financial reporting unless and until the entity's liquidation becomes imminent. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued.

The management uses quantitative and qualitative information, such as the Company's financial conditions and liquidity sources, its anticipated obligations, the funds necessary to maintain the entity's operations considering its current financial condition, obligations, and other expected cash flows within one year after the date that the financial statements are issued. Evaluating the reasonableness of these estimations and the assumptions requires a significant amount of judgement and is therefore subject to an inherent risk of error.

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 tranche by tranche based with an accelerated vesting over the 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, 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.

Taxes
Deferred tax assets are recognised for tax credits to the extent that it is probable that taxable profit will be available against which the credits can be utilised. Atai does not recognize deferred tax asset for the operating losses it incurred until more evidence of recoverability is available. We further refer to note 5.9 below.

4. 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.

Capital management and liquidity risk

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern and provide returns for shareholders. The Group monitors its capital on a regular and continuous basis, ensuring sufficient capital is in place for the Group's ongoing trading requirements.

As of December 31, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $109.2 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 Annual Report.

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

The Company believes that the cash and cash equivalents will be sufficient to fund projected operating expenses and capital expenditures through at least the next 12 months from the date of this annual report. The Company expect to incur substantial additional expenditures in the near term to support ongoing activities. Additionally, the expectation is additional costs will be incurred as a result of operating as a public company. The Company

expect to continue to incur net losses for the foreseeable future. The ability to fund product development and clinical operations as well as commercialization of product candidates, will depend on the amount and timing of cash received from planned financings.

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 preclinical studies, clinical trials and other related activities for ongoing and planned clinical trials, and potential future clinical trials;
- the costs of commercialization activities for any 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 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 in the Group companies upon the achievement of specified development milestone events;
- the cash requirements for developing programs 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 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.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments, and all notes receivables. The Company's cash is mainly held in financial institutions in the United States, United Kingdom, Germany and Australia. Amounts on deposit may at times exceed federally insured limits. The credit risk associated with the Company's investment in all notes receivables is monitored and assessed periodically. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

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.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2023, we had cash and cash equivalents of $45.0 million and short-term securities of $108.9 million. We generally hold our cash in interest-bearing demand deposit accounts and short-term securities. Due to the nature of our cash and investment portfolio, a hypothetical 100 basis point change in interest rates would not have a material effect on the fair value of our cash. Our cash is held for working capital purposes. The Company purchases investment grade marketable debt securities which are rated by nationally recognized statistical credit rating organizations in accordance with its investment policy. This policy is designed to minimize the Company's exposure to credit losses and to ensure that the adequate liquidity is maintained at all times to meet anticipated cash flow needs.

As of December 31, 2023, we had $0.4 million in convertible promissory notes – related parties, net, which was comprised of non-interest-bearing borrowings under the 2018 Convertible Notes. Based on the principal amounts of the convertible promissory notes and the interest rate assigned to the convertible promissory notes, an immediate 10% change in interest rates would not have a material impact on our convertible promissory notes, financial position or results of operations.

As of December 31, 2023, the carrying amount of our short and long-term notes receivables was an aggregate amount of $11.8 million. Based on the principal amounts of the notes receivable and the interest rates assigned to each note receivable as per their respective contracts, an immediate 10% change in the interest rates would not have a material impact on our notes receivables, financial position or results of operations.

5. Notes to the Consolidated Statements of Profit & Loss and Other Comprehensive Income (Loss)

5.1 Revenue

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

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

5.2 Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including discovery efforts and the development of 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.

R&D expenses consist of the following:

	12.31.2023	**12.31.2022**
	USD ‘000	USD ‘000
Direct research and development expenses for the subsidiaries	33.926	44.003
Personnel expenses	26.819	30.893
Professional and consulting services	1.952	1.006
Other	505	588
Total	**63.202**	**76.490**

Research and development expenses were $63.2 million for the year ended December 31, 2023, compared to $76.5 million for the year ended December 31, 2022. The decrease of $13.3 million was primarily attributable to a decrease of $10.1 million of direct costs in our programs as discussed below, a $4.1 million decrease in personnel expenses and a $0.9 million increase in professional and consulting fees.

Psychedelic Programs

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

IBX-210 & DMX-1002: Ibogaine for Opioid Use Disorder
The $1.9 million decrease in direct costs for our DMX-1002 program was primarily due to a decrease of $1.7 million of clinical development costs, a decrease of $0.1 million of manufacturing costs, and a decrease of $0.1 million of personnel and other related costs for the conduct of our Phase 1/2 trial to evaluate its safety, tolerability, PK, and efficacy in recreational drug users and healthy volunteers.

EMP-01: 3,4-methylenedioxy-methamphetamine (MDMA) derivative for Post Traumatic Stress Disorder
The $1.7 million decrease in direct costs for our EMP-01 program was primarily due to a decrease of $2.5 million preclinical development costs and a $0.7 million decrease of manufacturing costs, partially offset by an increase of $1.5 million in clinical development costs relating to our Phase 1 single ascending dose trial to assess the safety and tolerability of orally administered EMP-01.

EGX-A & EGX-B: Novel 5-HT2A Receptor Agonists
The $0.6 million increase in direct costs for EGX-A & EGX-B was primarily due to an increase in $0.6 million of preclinical development costs.

Non-psychedelic Programs

RL-007: Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia
The $5.6 million increase in direct costs for our RL-007 program was primarily due to an increase of $5.6 million of clinical development costs relating to our Phase 2b proof-of-concept clinical trial for RL-007 in CIAS.

Other Programs

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

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

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

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

5.3 Acquisition of in-process research and development

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

5.4 General 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.

G&A expenses consist of the following:

	12.31.2023	12.31.2022
	USD '000	USD '000
Personnel expenses	36.080	51.544
Professional and consulting services	18.889	17.626
Insurance	3.692	5.472
Restructuring	1.357	-
Facilities & IT	2.519	2.129
Other	3.412	2.454
Total	**65.948**	**79.225**

General and administrative expenses were $65.9 million for the year ended December 31, 2023 compared to $79.2 million for the year ended December 31, 2022. The decrease of $13.3 million was primarily related to a $15.5 million decrease in personnel expenses, a $1.8 million decrease in investor relations and public company compliance expenses, and a $1.8 million decrease in insurance expenses; partially offset by an increase of $3.3 million in non-income tax expense and a $2.5 million increase in professional consulting services & legal costs.

The average monthly number of persons employed by the Group (including directors remunerated by the Group) during the year, analysed by country, was as follows:

	Year ended 31 December 2023 Number	Year ended 31 December 2022 Number
Germany	**15**	**19**
United States	**54**	**85**
UK	**16**	**17**
Australia	**0**	1
Netherlands	**1**	1
	86	**123**

For key management personnel remuneration, see note 8.8.

5.5 Personnel Expense

Personnel expenses are split functionally between Research and development expenses and General Administrative in the Statement of Profit & Loss. The total personnel cost is summarised by function is below:

	31.12.2023 USD '000	31.12.2022 USD '000
Research and development expenses		
Wages & Salaries	10.456	10.542
Social security costs	685	800
Share Based Compensation	13.547	18.500
Bonus	898	2.124
Other benefits	1.233	1.311
Total	**26.819**	**33.277**
General administrative expenses		
Wages & Salaries	10.339	11.682
Social security costs	821	1.438
Share Based Compensation	22.549	34.926
Bonus	1.298	2.224
Other benefits	1.073	1.274
Total	**36.080**	**51.544**
Total personnel expenses		
Wages & Salaries	20.794	22.224
Social security costs	1.505	2.238
Share Based Compensation	36.096	53.426
Bonus	2.196	4.348
Other benefits	2.306	2.585
Total	**62.897**	**84.821**

5.6 Auditors' remuneration

Deloitte served as atai's independent registered public accounting firm during 2023 and 2022, and no relationship exists other than the usual relationship between such a firm and its client. Details about the nature of the services provided by, and fees atai paid to, Deloitte and affiliated firms for such services during 2023 and 2022 are set forth below.

	31.12.2023 USD '000	31.12.2022 USD '000
Audit of the financial statements – Deloitte & Touche LLP	3.015	3.080
Audit of the financial statements - Deloitte Accountants B.V.	268	246
Other audit engagement	-	-
Tax advisory	-	-
Other non-audit services	5	3
Total	**3.288**	**3.329**

5.7 Finance Income and Expense

	31.12.2023	31.12.2022
	USD '000	USD '000
Financial Income/(expense)	1.847	548
Foreign exchange gain (loss), net	(894)	6.902
Total Finance Income	**953**	**7.450**

Interest Income Interest income consists of interest earned on cash balances held in interest-bearing accounts and interest earned on notes receivable.

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.

5.8 Other Income (Expense)

In USD Thousands	12.31.2023	12.31.2022
	USD '000	USD '000
Benefit from research and development tax credit	2.445	-
Change in the fair value measurement	86.583	2.083
Impairments of other investments	(1.011)	-
Other Income (expense)	(2.845)	(1.412)
Total other income	**85.172**	**671**

Benefit from research and development tax credit

Benefit from research and development tax credit includes a research and development tax credit from the Australian Tax Authorities.

Change in the fair value measurement

During the year ended December 31, 2023, we recognized a $82.0 million change in fair value relating to our COMPASS investment, resulting from an accounting method change in which we were required to fair value the investment following our loss of significant influence, as well as an immaterial change in the fair value of our IntelGenx investment. The change in accounting methodology for our COMPASS investment happened in August 2023 creating a $78.8m gain, the increase to $82.0m at year end is directly driven by market share price.

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

In December 2023, certain 2020 convertible noteholders exchanged the 2020 convertible notes issued by ATAI Life Sciences AG for notes issued by ATAI Life Sciences N.V., which are convertible into ATAI NV common shares. We determined that this was a modification to the convertible note and record the fair value of the conversion

option quarterly. For the year ended December 31, 2023, we recognized a $0.7 million loss to a change in the fair value of the conversion option of the notes issued by ATAI Life Sciences N.V.

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

During the year ended December 31, 2023 & 2022, 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

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

Impairment of other investments

For the year ended December 31, 2023, we recognized a $1.0 million impairment of our DemeRx NB investment, which was transferred to DemeRx, Inc. in connection with our acquisition of the remaining equity in DemeRx IB.

Other expense, net

Other expense, net consists principally of interest expense and an impairment of a loan receivable. Interest expense consists primarily of interest expense incurred in connection with our term loan under the Loan Agreement entered into in August 2022. Upon closing of the Loan Agreement, Hercules Capital, Inc. issued a term loan advance in the amount of $15.0 million.

5.9 Profit on disposal of subsidiary

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

Psyber, Inc.

In October 2023, the Company entered into a Framework Agreement with the founders of Psyber, Inc. ("Founders") through which the Company transferred its equity interest in Psyber, Inc. ("Psyber") to the Founders in exchange for certain intellectual property.

As a result of the disposition, the Company ceased having controlling financial interest in Psyber. The Company determined that it was no longer the primary beneficiary, no longer had the power to direct the significant activities of Psyber, and accordingly, deconsolidated Psyber. The Company derecognized all of Psyber's assets and liabilities, with the exception of the retained intellectual property, from its consolidated balance sheet and recognized a loss of $0.3 million, which was reported as Loss on deconsolidation of a variable interest entity, a component of other income, net in the consolidated statement of operations for the year ended December 31, 2023.

The Company concluded that the decision to deconsolidate Psyber, which was based on resource capital allocation decisions, did not represent a significant strategic shift that would have a material effect on the Company's operations and financial results. Therefore, the Company did not present the results of Psyber prior to deconsolidation as discontinued operations in its consolidated statements of operations for the year ended December 31, 2023.

TryptageniX, Inc.

In December 2023, the Company finalized and entered into a Framework Agreement with CB Therapeutics, Inc. ("CBT") through which the Company transferred its equity interest in TryptageniX Inc. ("TryptageniX") to CBT in exchange for certain intellectual property and an Amended and Restated Development Services and Exclusive License Agreement.

As a result of the disposition, the Company ceased having controlling financial interest in TryptageniX. The Company determined that it was no longer the primary beneficiary, no longer had the power to direct the significant activities of TryptageniX, and accordingly, deconsolidated TryptageniX. The Company derecognized all of TryptageniX's assets and liabilities from its consolidated balance sheet, and recognized a gain of $0.4 million, which was reported as Gain on deconsolidation of a variable interest entity, a component of other income, net in the consolidated statement of operations for the year ended December 31, 2023.

The Company concluded that the decision to deconsolidate TryptageniX, which was based on resource capital allocation decisions, did not represent a significant strategic shift that would have a material effect on the Company's operations and financial results. Therefore, the Company did not present the results of TryptageniX prior to deconsolidation as discontinued operations in its consolidated statements of operations for the year ended December 31, 2023.

Neuronasal, Inc.

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

As a result of the disposition, the Company ceased having controlling financial interest in Neuronasal. The Company determined that it was no longer the primary beneficiary, as it no longer had the power to direct the significant activities of Neuronasal, and accordingly deconsolidated Neuronasal. Upon the effective termination date, the Company derecognized all of Neuronasal's assets and liabilities from its balance sheet, and recognized a gain of $1.5 million, which was reported as Gain on deconsolidation of a variable interest entity, a component of other income, net in the consolidated statement of operations for the year ended December 31, 2022. The Company determined that the value of the warrants received in connection with the Termination Agreement were de minimis as of the termination date and continue to be de minimis as of the year ended December 31, 2023. In connection with the deconsolidation of Neuronasal, the Company concluded that the loan assets were impaired and recognized an impairment of $0.9 million, which was reported in Other income(expense), net in the consolidated statements of operations for the year ended December 31, 2022.

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

5.10 Income tax

For our consolidated entities, deferred income taxes are provided for the net effects of temporary differences between the carrying amounts of assets and liabilities recognised for financial reporting purposes and the amounts recognised for income tax purposes, to the extent that it is probable that future taxable profit will be available.

atai regularly assess the availability and probability of future taxable profits, to (re)confirm its estimate that some or all of the deferred tax assets are more likely than not to will be realized. Accordingly, certain German and international tax loss carry forwards and temporary timing differences related to share-based compensation are not recognised as deferred tax assets, as they are assessed to be not more-likely-than-not to be realized. We recognise 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 carry forward 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 carry back and carry forward periods), future projected taxable income, including the character and jurisdiction of such income, and tax-planning strategies in making this assessment.

Unrecognised 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, 2023 and December 31, 2022, atai did not have any unrecognised tax benefits

	12.31.2023	**12.31.2022**
	USD '000	USD '000
Total current income tax provision (benefit)	1.016	1.155
Deferred income tax provision	-	5.074
Total tax provision (benefit)	**1.016**	**6.229**

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

	12.31.2023	**12.31.2022**
	USD '000	USD '000
Germany	20.759	(57.885)
International	(63.407)	(88.349)
Total loss before income taxes and loss from equity method investments	(42.648)	(146.234)

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

	12.31.2023	**12.31.2022**
	USD '000	USD '000
Current income tax provision (benefit):		
Germany	-	-
International	1.016	1.155
Total current income tax provision:	1.016	1.155
Deferred income tax provision (benefit):	-	-
Germany	-	-
International	-	5.074
Total deferred income tax provision:	-	5.074
Total income tax provision:	1.016	6.229

The international current tax provision for December 31, 2023 and 2022 is primarily comprised of corporate income taxes incurred in the United States 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):

	12.31.2023 USD '000	12.31.2022 USD '000
Loss before income taxes:		
Germany	20.759	(57.898)
International	(63.407)	(88.336)
Total loss before income taxes:	(42.648)	(146.234)
German statutory rate	30,18%	30,18%
Expected income tax expense (benefit)	(12.871)	(44.133)
Net US state income taxes	(3.662)	(6.509)
International tax rate differential	5.188	7.276
Effect of R&D credit incentives	582	(338)
Fair value adjustments	-	(109)
Effect of consolidation and deconsolidation of subsidiaries	3.250	(1.394)
Capitalised equity transaction costs, which are expensed under local GAAP	-	98
Compensation Expenses not deductible under IRC Section 162(m)	1.368	411
Expenses/(benefit) not deductible for tax purposes	600	(324)
Effect of share-based compensation expense	975	217
Other	10.188	758
Uncertain tax positions	96	-
Change in unrecognised temporary differences during reporting period	(4.698)	50.277
Total income tax expense/(benefit)	1.016	(6.229)
Effective income tax rate:	-2,59%	-4,26%

The Company is headquartered in Berlin, Germany and has subsidiaries in the United States, Australia, the United Kingdom, and Singapore as well as minority investments in Canada, Germany, and the United Kingdom. The Company incurred tax losses in most jurisdictions, however, generated taxable profits in certain United States subsidiaries, United Kingdom, and Australian subsidiaries. The weighted-average combined German corporate income tax rate for the year ended December 31, 2023 and 2022 was 30.18% ((inclusive a corporate income tax rate of 15.00%, solidarity surcharge of 0.83%, and trade tax rate of 14.35%). The weighted-average United States corporate income tax rate for year ended December 31, 2023 and 2022 was 21.00%. The weighted-average Australia corporate income tax rate for the year ended December 31, 2023 and 2022 was 25.00%. In 2023 it was noted that atai Therapeutics Pty Ltd would not qualify for the reduced rate under the base rate entity ("BRE") test as the amount of passive income exceed 90% of total income. This entity was therefore subject to a 30% tax rate. The weighted-average United Kingdom corporate income tax rate for the year ended December 31, 2023 and 2022 was 25.00% and 19.00%, respectively. The Singapore corporate income tax rate for the year ended December 31, 2023 was 17.00%.

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

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

	12.31.2023 USD '000	12.31.2022 USD '000
Deferred tax assets:		
Net tax loss carry forward and other timing differences	30.830	5.384
Total deferred tax assets, net	30.830	5.384
Deferred tax liabilities:		
Other taxable timing differences	(930)	(908)
Unrealized foreign exchange	(4.904)	(4.472)
Outside basis differences in equity and other investments	(2)	(4)
Investments	(24,982)	
Operating lease right-of-use asset	(12)	
Total deferred tax liabilities	(30.830)	(5.384)

atai reported gross recognized and unrecognized deferred tax assets of $120.8 million for the period ended December 31, 2023, primarily related to German and international tax loss carry forwards, capitalized research and experimental costs, and stock-based compensation timing differences. Of this amount, $30.8 million of deferred tax assets are recognized against deferred tax liabilities that are expected to reverse. The remaining $90.0 million of deferred tax assets are unrecognized as, in the judgment of f management, such deferred tax assets are not more-likely-than-not to be realized.

As relevant to certain United States subsidiaries, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize certain research and experimental ("R&D") expenditures under Internal Revenue Code ("IRC") Section 174 for tax years beginning after December 31, 2021 resulting in the capitalization of certain R&D costs within the Company's tax provision in 2023 and 2022. IRC Section 174 costs attributable to R&D performed in the United States and outside of the United States is amortizable over 5 years and 15 years, respectively. The majority of the Company's R&D costs incurred in 2023 were performed outside of the United States and are amortizable over a 15 year period.

In assessing the realizability of deferred tax assets, management regularly considers whether it is more-likely-than-not that some or all of the recorded deferred tax assets will be realized. The future realization of deferred tax assets is subject to the existence of sufficient taxable income of the appropriate character (e.g., ordinary income or capital gain) as provided under the carryforward provisions of local tax law. Additionally, deferred tax assets with respect to tax losses in the United States may be subject to limitation as a result of ownership changes within the meaning of Section 382 of the IRC. Management considers the Company's limited history and historical tax losses, future projected taxable income, including the character and jurisdiction of such income, the scheduled reversal of deferred tax liabilities (including the effect in available carryback and carryforward periods), and tax-planning strategies in making this assessment. In the event that there is a change in the ability to recover deferred tax assets, our income tax provision would increase or decrease in the period in which the assessment is changed.

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

The Company has limited prior earnings history and, due to the early stages of its development and research activities, is expected to generate losses for the next several years and cannot accurately estimate future profit projections beyond such time. As such, management believes that it is more likely than not that the Company will not realize the benefits of such tax loss carryforwards and deductible differences.

As of December 31, 2023 and 2022 the Company did not have any significant unremitted earnings in its foreign subsidiaries.

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

	12.31.2023	12.31.2022
	USD '000	USD '000
Germany tax losses	162.436	150.991
International tax losses	56.691	41.908
Total	219.127	192.899

The Company's tax loss carryforwards have an indefinite carryforward period, however, for tax years 2021 and beyond, in the United States, utilization of certain tax losses may not exceed 80% of United States taxable income in any one year, computed without regard a deduction for tax losses utilized.

The Company's 2020 through 2023 tax returns are currently open to audit. The 2021 tax return for Perception Neuroscience Holdings, Inc. is currently under routine audit by the Internal Revenue Service. The Company is not under examination for any other entity.

5.11 Losses from Investments in Equity Method Investees, Net of Tax

Losses from investment in equity method investees for the years ended December 31, 2023 and 2022 were $3.6 million and $16.0 million, respectively. We recorded a $10.1 million loss in 2022 related to our COMPASS investment, which reduced the investment carrying value to zero. No further loss was recorded in 2023. The loss related to our GABA Therapeutics, Inc investment decreased by $2.3 million year-over-year.

5.12 Net Loss Attributable to Noncontrolling Interests

Net loss attributable to noncontrolling interests in our consolidated statements of operations is a result of our investments in certain of our consolidated subsidiaries and consists of the portion of the net loss of these consolidated entities that is not allocated to us. Net losses in consolidated subsidiaries are attributed to noncontrolling interests considering the liquidation preferences of the different classes of equity held by the shareholders in the subsidiary and their respective interests in the net assets of the consolidated subsidiary in the event of liquidation, and their pro rata ownership. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by changes in the net loss of our subsidiaries and our ownership percentage changes.

6. Notes to the consolidated statement of financial position

6.1 Equity method investments

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

		As of December 31, 2023			As of December 31, 2022		
Investee	Date First Acquired	Ownership %		Carrying Value	Ownership %		Carrying Value
Innoplexus A.G.	August 2018	35.0%		$ —	35.0%		$ —
COMPASS Pathways plc	December 2018	15.4%	(1)	$ —	22.87%		$ —
GABA Therapeutics, Inc	November 2020	54.01%	(2)	$ 1,838	53.82%	(2)	$ 5,387
IntelGenx Technologies Corp.	May 2021	24.13%	(3)	$ —	21.36%	(3)	$ —
Total				$ 1,838			$ 5,387

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

(2) The Company is deemed to have significant influence over GABA Therapeutics, Inc ("GABA") through its total ownership interest in GABA, including the Company's investment in GABA's. The Company's total ownership interest, considering both preferred and common stock is 54.7%. The Company does not have control over GABA due to having no board seat.

(3) The Company's investment in Intelgenx common stock has been written down to zero due to loss allocation. The Company still holds convertibles notes, warrants and call options in Intelgenx. Please see notes 6.3 & 6.4 for detail.

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 initial proceeds from the transaction are reflected as a secured borrowing liability of $2.4 million as of December 31, 2023 and 2022, which is included in Other liabilities in the Company's consolidated balance sheets. The Company will continue to account for its investment in Innoplexus' common stock under the equity method.

In addition, the Innoplexus SPA also provides the rights for the Company to receive additional consideration with a maximum payment outcome of $22.3 million should the equity value of Innoplexus exceed certain thresholds upon the occurrence of certain events. The Company concluded that this feature met the definition of a derivative which required bifurcation. As the probability of the occurrence of certain events defined in the

Innoplexus SPA was less than remote, the Company concluded that the fair value of the embedded derivative ascribed to this feature was de minimis as of December 31, 2023 and 2022.

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

COMPASS Pathways plc

COMPASS Pathways plc ("COMPASS") is a mental health care company dedicated to pioneering the development of a new model of psilocybin therapy with its product COMP360. The Company first acquired investments in COMPASS in December 2018 with additional investments through 2021.The Company's ownership interest in COMPASS as of December 31, 2022, was 22.4%. In August 2023, COMPASS closed its most recent financing round, in which the Company did not participate, and the Company's ownership interest in COMPASS was reduced to 15.4%.

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

Following COMPASS's August 2023 financing, the Company evaluated its ability to continue to exercise significant influence over its investment and determined that it no longer had significant influence. The Company did not participate in this financing which result in a dilution of shares and the trigger for the revaluation of significant influence. Subsequent to this remeasurement date, the Company's COMPASS investment is accounted for at fair value under IFRS 9and recorded in Other investments on the consolidated balance sheets. Any changes in fair value of the Company's COMPASS investment are recorded as a Change in fair value measurement in its consolidated statements of profit & loss Based on quoted market prices, the fair value of the Company's COMPASS investment was $83.7 million as of December 31, 2023. For the year ended December 31, 2023, the Company recorded $82.0 million of Change in fair value measurement.

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.

The Company's investment in GABA's common & preferred stock was accounted for in accordance with the equity method.

In November 2020 the Company exercised its option to purchase additional shares of common stock of GABA at a price of approximately $1.8 million pursuant to an Omnibus Amendment Agreement under which the Right of First Refusal and Co-Sale Agreement was amended. Pursuant to the amended Right of First Refusal and Co-Sale Agreement, the Company also has the option but not the obligation to purchase additional shares of common stock for up to $2.0 million from the existing common shareholders.

The carrying value of the investment in GABA common stock was reduced to zero as of December 31, 2020 due to IPR&D charges with no alternative future use and remained zero as of March 31, 2023.

In August 2019, GABA and the Company entered into the Preferred Stock Purchase Agreement (the "GABA PSPA"), whereby GABA issued shares of its Series A preferred stock to the Company at a price of approximately

$5.5 million. At closing, the Company had an overall ownership interest of over 20% in GABA and a noncontrolling representation on the board.

Pursuant to the GABA PSPA, the Company was obligated to purchase additional shares of Series A preferred stock for up to $10.0 million with the same price per share as its initial investment, upon the achievement of specified contingent clinical development milestones. In April 2021, pursuant to the GABA PSPA, the Company purchased additional shares of Series A preferred stock of GABA, for an aggregate cost of $5.0 million based on the achievement of certain development milestones. In May 2021, the Company exercised its option to purchase additional shares of Series A preferred stock prior to the achievement of certain development milestone for an aggregate cost of $5.0 million completing its obligation to purchase additional shares. 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.

In May 2021, GABA and the Company entered into an Amendment to Preferred Stock Purchase Agreement (the Amended GABA PSPA") under which the GABA PSPA was amended and shares of its Series A preferred stock were issued to the Company at a price of approximately $0.6 million. Pursuant to the Amended GABA PSPA, the Company is obligated to purchase additional shares of Series A preferred stock from GABA for up to $1.5 million with the same price per share as its initial investment upon the achievement of specified contingent clinical development milestones. In September 2022, pursuant to the Amended PSPA, GABA issued additional shares of its Series A preferred stock to the Company at a price of approximately $0.6 million based on the achievement of certain development milestones. As of March 31, 2023 the Company has a remaining obligation to purchase additional shares of Series A preferred stock from GABA for up to $0.9 million.

In accordance with the Amended GABA PSPA, the Company also has the option but not the obligation to purchase the aforementioned additional shares of Series A preferred stock at any time prior to the achievement of any milestone at the same price per share as its initial investment.

GABA's net losses attributable to the Company were determined based on the Company's ownership percentage in GABA and recorded to the Company's investments in GABA. The carrying value of $1.838m at December 31, 2023 is a result of the investments noted above, less accumulated losses over the period since investment.

Summarized Financial Information
The following is a summary of financial data for investments accounted for under the equity method of accounting (in thousands):

Balance Sheets

	December 31, 2023
	GABA
Current assets	$ 1,720
Non-current assets	—
Total assets	$ 1,720
Current liabilities	$ 1,546
Non-current liabilities	—
Total liabilities	$ 1,546

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

Statements of operations

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

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

(1) As of August 18, 2023, the Company determined that it no longer had significant influence. At this remeasurement date, the Company qualified for and elected to account for its investment in COMPASS under the fair value option. Summarized financial information is as of and for the nine month period ending September 30, 2023 as this information is not readily available as of August 18, 2023 and the Company has no practical way to estimate otherwise.

IntelGenx Technologies Corp.

IntelGenx is a novel drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market. In March 2021, IntelGenx and the Company entered into the Strategic Development Agreement and Purchaser Rights Agreement ("PPA").

Securities Purchase Agreement

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

Following the initial closing, the Company held a 25% voting interest in IntelGenx. Pursuant to the PPA, the Company is entitled to designate a number of directors to the IntelGenx's board of directors in the same proportion as the shares of common stock held by the Company to the outstanding of IntelGenx common shares. The Company has significant influence over IntelGenx through the Company's ownership interest in IntelGenx's equity and its noncontrolling representation on IntelGenx's board of directors.

The Initial Warrants and the Additional Units Warrant are accounted for at fair value under IFRS 9 and recorded in financial fixed assets – related parties on the consolidated balance sheets. The Company applied a calibrated model and determined that the initial aggregate fair value of its $12.3 million investment was equal to the transaction price and recorded the common shares at $3.0 million, the Initial Warrants at $1.2 million and the Additional Unit Warrants at $8.2 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of profit & loss. The Company recognizes subsequent changes in fair value of the Initial Warrants and the Additional Unit Warrants as Change in fair value measurement , a component of other income (expense), net in the consolidated statements of profit & loss. The carrying amount of the investment & warrants was reduced to zero as of December 31, 2021. During the years ended December 31, 2023 and 2022, the Company did not recognize a change in fair value in the consolidated statements of profit & loss. The carrying value of the investment & warrants remained at zero as of December 31, 2023 and 2022.

Subscription Agreement, as amended

In August 2023, IntelGenx and the Company entered into a subscription agreement (the “Subscription Agreement”), under which the Company paid IntelGenx $2.2 million for 2,220 convertible debenture units (the "2023 Initial Units"), with each convertible debenture unit consisting of:

(i) $1,000 principal amount convertible promissory notes (the “2023 Initial Notes”) bearing interest at a rate of 12.0% per annum, payable quarterly in arrears beginning September 30, 2023, with all principal and accrued interest convertible into common shares of IntelGenx, at any time from the date that is six months following their issuance up to and including August 31, 2026 at a conversion price equal to $0.185 per common share; and

(ii) 5,405 common share purchase warrants of IntelGenx (the “2023 Initial Warrants”), each exercisable at an exercise price of $ 0.26 per common share for a period of three years following their issuance.

Pursuant to the Subscription Agreement, the Company agreed to subscribe for an additional 750 convertible debenture units (the "2023 Subsequent Units") at a price of $750,000 subject to obtaining certain shareholder approvals. The Subsequent Units contain the same terms as the Initial Units, with each Subsequent Unit consisting of (i) $1,000 principal amount convertible promissory notes ("2023 Subsequent Notes") and (ii) 5,405 common share purchase warrants of IntelGenx ("2023 Subsequent Warrants").

Effective September 30, 2023 , IntelGenx and the Company amended the Subscription Agreement (the “Amended Subscription Agreement”), allowing the Company, subject to obtaining certain shareholder approvals, the "Call Option" to purchase up to an additional 7,401 convertible debenture units (the “Call Option Units”). The Call Option Units contain the same terms as the Initial Units, with each Call Option Unit consisting of (i) $1,000 principal amount convertible promissory notes, and (ii) 5,405 common share purchase warrants of IntelGenx.

The issuance of any Call Option Unit shall result in a corresponding reduction in the Company's remaining purchase right pursuant to the IntelGenx SPA executed in May 2021 (the “2021 Purchase Right”), with such right to be reduced by the maximum number of shares of common stock issuable in connection with such Call Option Units, and (ii) in the event that the 2021 Purchase Right has been fully or partially exercised such that the aggregate number of shares of common stock issued thereunder together with the number of shares of common stock issuable in accordance with the Call Option Units would exceed 100,000,000, the number of shares of common stock that may be issued in connection with the Call Option Units shall be reduced such that the aggregate number of shares of common stock issued thereunder together with the number of shares of common stock issuable in accordance with the Call Option Units does not exceed 100,000,000. The maximum number of shares of common stock available under the 2021 Purchase Right was reduced from 130,000,000 shares of common stock to 100,000,000 shares of common stock, such that in no event shall the aggregate number of shares of common stock issuable in accordance with the Call Option Units and the 2021 Purchase Right exceed 100,000,000.

There are limits over the conversion of the Initial Units, Subsequent Units, Call Options Units and the IntelGenx Term Loan into common shares.

The Company qualified for and elected to account for its investment in the convertible debenture units and call option under the fair value option. The Company believes that the fair value option better reflects the underlying economics of the convertible debenture units and call option. The convertible promissory notes are accounted for at fair value and recorded in Convertible notes receivable - related party in the consolidated balance sheet, as described further in Note 6. The warrants and call option are accounted for pursuant to the fair value option election and recorded in Financial fixed assets – related parties in the consolidated balance sheet.

For the Initial Units, the Company applied a calibrated model and determined that the initial aggregate fair value of its $2.2 million investment was equal to the transaction price and recorded the 2023 Initial Notes at $1.5 million and the 2023 Initial Warrants at $0.7 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of profit & loss. The Company will recognize subsequent changes in fair value of the Initial Units as Change in fair value measurement, a component of other income (expense), net in the consolidated statements of profit & loss. As of December 31, 2023, the fair value of the 2023 Initial Warrants was $0.7 million. For the year ended December 31, 2023, the Company recognized an immaterial amount in Change in fair value of assets and liabilities, net relating to the 2023 Initial Warrants in its consolidated statements of profit & loss.

In November 2023, upon shareholder approval, the Company paid $750,000 for the 2023 Subsequent Units. The Company applied a calibrated model and determined that the initial aggregate fair value of its $0.8 million investment was equal to the transaction price and recorded the 2023 Subsequent Notes at $0.6 million and the 2023 Subsequent Warrants at $0.2 million on a relative fair value basis resulting in no initial gain or loss recognized in the consolidated statements of profit & loss. The Company will recognize subsequent changes in fair value of the Subsequent Units as Change in fair value measurement, a component of other income (expense), net in the consolidated statements of profit & loss. As of December 31, 2023, the fair value of the 2023 Subsequent Warrants was $0.2 million. For the year ended December 31, 2023, the Company recognized an immaterial amount in Change in fair value measurement relating to the 2023 Subsequent Warrants in its consolidated statements of profit & loss.

In November 2023, upon shareholder approval, the Call Option had an estimated fair value of $5.1 million and is recorded in financial fixed assets – related parties in the consolidated balance sheet. The Call Option is additional value conveyed to the Company relating to its investment in and Strategic Development Agreement with IntelGenx. Accordingly, the Company has also recorded a $5.1 million deferred credit, included in Other liabilities in the consolidated balance sheet. As appropriate, the Company will account for the deferred credit as a reduction of research and development expense in its consolidated statements of operation until the credit is exhausted or the Company is no longer receiving goods or services from IntelGenx. As of December 31, 2023, the fair value of the Call Option was $5.2 million. For the year ended December 31, 2023, the Company recognized $0.1 million in Change in fair value measurement relating to the Call Option in its consolidated statements of profit & loss.

Strategic Development Agreement

Pursuant to the Strategic Development Agreement, the Company engages IntelGenx to conduct research and development projects (“Development Project”) using IntelGenx’s proprietary oral thin film technology. Under the terms of the Strategic Development Agreement, the Company can select four (4) program products. As of the effective date of the Strategic Development Agreement, the Company nominated two (2) program products - DMT and Salvinorin A. 20% of any funds that IntelGenx received or will receive through the Company’s equity investment under the IntelGenx SPA will be available to be credited towards research and development services that IntelGenx conducts for the Company under the Development Projects. The Company is eligible to receive a total credit of $2.5 million. For the years ended December 31, 2023 and 2022, research and development expense relating to the Strategic Development Agreement were $0.7 million and $0.5 million, respectively, which was applied as a reduction in research and development expenses in accordance with the Strategic Development Agreement.

6.2 Other Investments

As of December 31, 2023 and December 31, 2022, the carrying values of other investments were as follows (in thousands):

	12.31.2023	12.31.2022
	USD '000	USD '000
DemeRx NB, Inc.	-	1,024
Juvenescence Limited	-	344
COMPASS Pathways plc	83,700	-
Total	**83.700**	**1,368**

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

DemeRX NB, Inc

In December 2019, the Company jointly formed DemeRx NB, Inc. ("DemeRx NB") with DemeRx Inc. DemeRx Inc. and DemeRx NB entered into a Contribution Agreement whereby DemeRx inc. assigned all of its rights, title, and interests in and to all of its assets relating to DMX-1002, Noribogaine, in exchange for shares of common stock of DemeRx NB. DemeRx NB will use the contributed intellectual property to develop Noribogaine. Noribogaine is an active metabolite of ibogaine designed to have a longer plasma half-life and potentially reduced hallucinogenic effects compared to ibogaine.

In connection with the Contribution Agreement, the parties entered into a Series A Preferred Stock Purchase Agreement (the "DemeRx NB PSPA") pursuant to which the Company purchased shares of Series A preferred stock of DemeRx NB at a purchase price of $1.0 million. At closing, the Company had less than 20% of ownership interest in DemeRx NB and a noncontrolling representation on DemeRx NB's board of directors. The investment in DemeRx NB was recorded in Other investments on the consolidated balance sheet.

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.'s equity ownership of DemeRx IB (the "Stock Purchase"), in exchange for consideration that included, among other items, the transfer of the Company's ownership in DemeRx, NB, Inc. to DemeRx, Inc. In connection with the Stock Purchase, the Company assessed the fair market value of its DemeRx NB investment and determined that it had been impaired. As a result, the Company recognized a $1.0 million impairment loss in Impairment of other investments, a component of other income, net in the consolidated statements of operations for the year ended December 31, 2023.

Juvenescence Limited

As of December 31, 2022 the Company's investment in Juvenescence Limited ("Juvenescence") was in common stock, however, it was not able to exercise significant influence over the operating and financial decisions of Juvenescence. During the year ended December 31, 2023, the Company divested its investment in Juvenescence Limited ("Juvenescence") and recognized a $0.1 million gain on the transaction reflected in Other income (expense), net on the consolidated statements of operations.

6.3 Financial fixed assets – related parties

As of December 31, 2023, financial fixed assets – related parties consists of the initial 2023 warrants, subsequent 2023 warrants and call option with Intelgenx.

	12.31.2023	12.31.2022
	USD '000	USD '000
IntelGenx Corp.	6.125	-
Total	**6.125**	**-**

Further details on the warrants and call option are disclosed in footnote 6.2 Other Investments.

6.4 Convertible notes receivable - related parties

As of December 31, 2023, convertible note receivable – related parties consists of the initial 2023 notes, subsequent 2023 notes and amended 2021 term loan agreements with Intelgenx.

	12.31.2023	12.31.2022
	USD '000	USD '000
IntelGenx Corp.	11.202	-
Total	**11.202**	**-**

The fair value of the 2023 Initial Notes, 2023 Subsequent Notes ,and the IntelGenx Term Loan (collectively "Convertible Notes") at issuance were estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The initial cost of the notes & term loan was $12.7m.

The fair value of the 2023 Initial Notes and the 2023 Subsequent Notes is estimated using a Binomial Lattice in a risk-neutral framework (a special case of the Income Approach). Specifically, the future stock price of the IntelGenx is modelled assuming a Geometric Brownian Motion in a risk-neutral framework. For each modelled future price, the 2023 Initial Notes and the 2023 Subsequent Notes is calculated based on the contractual terms (incorporating any optimal early exercise), and then discounted at the term-matched risk-free rate. Finally, the value of the 2023 Initial Notes and the 2023 Subsequent Notes is calculated as the probability-weighted present value over all future modelled payoffs. The fair value of the 2023 Initial Notes and 2023 Subsequent Notes was $1.7 million and $.05 million, respectively, and recorded in Convertible notes receivable - related party in the consolidated balance sheets as of December 31, 2023.

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

The fair value of the IntelGenx Term Loan was estimated as the present value of the debt cash-flows plus the fair value of the Conversion Feature. The Conversion Feature fair value was estimated utilizing the Black-Scholes option pricing model. The Black Scholes option pricing model is based on the estimated market value of the underlying common stock at the valuation measurement date, the remaining contractual term of the Conversion Feature, risk-free interest rates, expected dividends, and expected volatility of the price of the underlying common stock. The expected volatility is based on a peer group volatility which is a Level 3 input within the fair value hierarchy. As of December 31, 2023, the $8.6 million fair value of the amended IntelGenx Term Loan was recorded in Convertible notes receivable – related party on the consolidated balance sheet.

The significant unobservable inputs that are included in the valuation of the IntelGenx Term Loan as of December 31, 2023 are (i) discount rate of 45.9% based on an assessment of IntelGenx credit risk and market yields of

companies with similar credit risk, (ii) volatility of 100% and (iii) estimated market value of the underlying common stock of $0.13.

6.5 Other assets

	12.31.2023	12.31.2022
	USD '000	USD '000
Other assets	3.943	3.351
Total	3.943	3.351

Included in other assets is $1.8 million (2022: $1.6m) intangible assets which are considered immaterial.

6.6 Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2023 and December 31, 2022, cash and cash equivalents consisted of cash on deposit and cash held in high-yield savings accounts and money market funds.

6.7 Securities held at fair value

The Company elected the fair value option for the securities in its investment portfolio (level 2). The fair value is based on quoted market prices, when available. When a quoted market price is not readily available, the Company uses the market price from its last sale of similar assets.

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

The unrealized gains and losses on the available-for-sale securities, represented by change in the fair value of the investment portfolio, is reported in earnings. Since the investment in the available-for-sale securities are already measured at fair value, no separate credit losses would be recorded in the financials.

For the year-ended December 31, 2023 and 2022, the Company recognized a $5.5 million and $0.3 million gain related to the change in fair value change in its available for sale securities recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations.

6.8 Funds held in trust

As of December 31, 2023 the Company had $25.0 million of cash committed in anticipation of the closing of Beckley Psytech investment in January 2024. The investment closed on January 3rd and is disclosed within subsequent events.

6.9 Prepaid expenses and other current assets

Prepaid expenses consist of the following:

	12.31.2023	12.31.2022
	USD '000	USD '000
Prepaid research and development related expenses	1.822	4.626
Research and development tax credit	1.341	584
Sales tax receivables	411	5.046
Prepaid insurance	1.410	2.034
Other	846	1.746

Total	**5.830**	**14.036**

6.10 Non-current portion of contingent consideration liability – related party

Non-current portion of contingent consideration liability, consisted of the following:

	12.31.2023	12.31.2022
	USD '000	USD '000
Current portion of contingent consideration liability	-	-
Non-Current portion of contingent consideration liability	620	953
Total contingent consideration liability – related party	**620**	**953**

Fair value of contingent consideration liability was assessed using level 3 measurements in the fair value hierarchy.

6.11 Non-current portion of contingent consideration liability

Non-current portion of contingent consideration liability, consisted of the following:

	12.31.2023	12.31.2022
	USD '000	USD '000
Current portion of contingent consideration liability	-	-
Non-Current portion of contingent consideration liability	1.637	-
Total contingent consideration liability	**1.637**	**-**

Fair value of contingent consideration liability was assessed using level 3 measurements in the fair value hierarchy.

6.12 Convertible promissory notes

Convertible promissory notes, consisted of the following:

	12.31.2023	12.31.2022
	USD '000	USD '000
Exchange of 2020 Convertible Promissory Notes	2.666	-
Total	**2.666**	**-**

In November 2023, a nonrelated party noteholder of the October 2020 notes and ATAI Life Sciences AG executed an exchange agreement ("2023 Exchange Agreement") where the noteholder agreed to exchange its 2020 convertible notes issued by ATAI Life Sciences AG ("Old AG Notes") into the same principal amount of new convertible notes issued by ATAI Life Sciences N.V. ("New NV Notes"). The New NV Note are non-interest-bearing, unsecured and are due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each New NV Note has a face value of €1 and is convertible into 16 common shares of ATAI Life Sciences N.V. upon the payment of €17.00. Conversion rights may be exercised by a noteholder at any time prior to maturity. The New NV Notes may be declared for early redemption by the

noteholders upon occurrence of specified events of default, including payment default, insolvency and a material adverse change in the Company's business, operations or financial or other condition. Upon early redemption, the conversion right with respect to the New NV Notes may no longer be exercised.

In December 2023, the Company and the same noteholder entered into a subscription agreement ("2023 Subscription Agreement") and exchanged its Old AG Notes into New NV Notes. The Company determined that the note exchange was a modification of the debt. The 2023 Exchange Agreement and 2023 Subscription Agreement resulted in the new NV Notes conversion option no longer meeting the equity classification criteria. Accordingly, at the time of the 2023 Exchange Agreement modification, the Company bifurcated the conversion option and reclassified the conversion option fair value from equity to a liability and is included in Convertible promissory notes and derivative liability in the consolidated balance sheet. The conversion option is measured at fair value on a quarterly basis and any changes in the fair value will be recorded as Change in fair value of assets and liabilities, net, a component of other income (expense), net in the consolidated statements of operations. For the year ended December 31, 2023, the Company recognized a loss of $0.7 million as a result of the change in fair value of the New NV notes.

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

6.13 Long Term Debt

Hercules Loan and Security Agreement

In August 2022, the Company and certain subsidiaries, as guarantors, and Hercules Capital, Inc. entered into a Loan and Security Agreement (as amended by that certain First Amendment to Loan and Security Agreement dated as of March 13, 2023, the "Hercules Loan Agreement"). The Loan Agreement provides for term loans in an aggregate principal amount of up to $175.0 million under multiple tranches (the "2022 Term Loan Facility"), available as follows: (i) a term loan advance in the amount of $15.0 million on the Closing Date (the "Tranche 1A Advance"); (ii) at any time after the Closing Date but on or prior to May 1, 2023 (the "Tranche 1B Expiration Date"), term loan advances in an aggregate principal amount of up to $20.0 million (the "Tranche 1B Advances"); (iii) at any time beginning upon the earlier of (A) the Tranche 1B Expiration Date and (B) the date on which all amounts available to be drawn under the Tranche 1B Advances have been drawn and on or prior to December 15, 2023 (the "Tranche 1C Expiration Date"), term loan advances in an aggregate principal amount of up to $25.0 million (the "Tranche 1C Advances" and together with the Tranche 1A Advance and the Tranche 1B Advances, the "Tranche 1 Advances"); (iv) subject to us achieving certain performance milestones and, beginning upon the earlier of (A) the date on which all amounts available to be drawn under the Tranche 1C Advances have been drawn and (B) the Tranche 1C Expiration Date, on or prior to June 30, 2024, term loan advances in an aggregate principal amount of $15.0 million (the "Tranche 2 Advances"); and (v) subject to approval by the Lenders' respective investment committees in its discretion, on or prior to March 31, 2025, term loan advances in an aggregate principal amount of up to $100.0 million (the "Tranche 3 Advances"). With the exception of the first $15.0 million tranche available on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at the Company's election, subject to applicable conditions to draw.

The 2022 Term Loan Facility will mature on August 1, 2026 (the "Maturity Date"), which may be extended until February 1, 2027 if the Company achieves certain performance milestones, raises at least $175.0 million of unrestricted new net cash proceeds from certain permitted sources after the Closing Date and prior to June 30, 2024, and satisfies certain other specified conditions. The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) the prime rate as reported in the Wall Street Journal plus 4.55% and (ii) 8.55%. Accrued interest is payable monthly following the funding of each term loan advance. The Company may make payments of interest only, without any loan amortization payments, for a period of thirty (30) months following the Closing Date, which period may be extended to (i) thirty-six months if certain additional performance milestones have been achieved; and (ii) forty-two months if certain additional performance milestones have been achieved. At the end of the interest only period, the Company is required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly instalments.

The Hercules Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favour of the Agent (the "Qualified Cash") at all times commencing from the Closing Date, which includes a cap on the amount of cash that can be held by, among others, certain of our foreign subsidiaries in Australia and the United Kingdom. In addition, the financial covenant under the Loan Agreement requires that beginning on the later of (i) July 1, 2023 and (ii) the date on which the aggregate outstanding amount borrowed under the 2022 Term Loan Facility is equal to or greater than $40.0 million, the Company shall maintain Qualified Cash in an amount no less than the sum of (1) 33% of the outstanding amount under the 2022 Term Loan Facility, and (2) the amount of the Borrowers' and Subsidiary Guarantors' accounts payable that have not been paid within 180 days from the invoice date of the relevant account payable, subject to certain exceptions; provided, that the financial covenant shall not apply on any day that the Company's market capitalization is at least $600.0 million measured on a consecutive 10-business day period immediately prior to such date of measurement and tested on a daily basis. Upon the occurrence of an event of default, including a material adverse effect, subject to certain exceptions, on ATAI NV and ATAI AG's, taken together, business, operations, properties, assets or financial condition, and subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by the Lenders. As of December 31, 2022 the Company was in compliance with all applicable covenants under the Hercules Loan Agreement.

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

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

The Company incurred financing expenses related to the Hercules Loan Agreement, which are recorded as an offset to long-term debt on the Company's consolidated balance sheets. These deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in other income (expense), net in the Company's consolidated statements of operations. During the years ended December 31, 2023 and 2022, respectively, interest expense included $0.4 million and $0.1 million of amortized deferred financing costs related to the 2022 Term Loan Facility.

Outstanding debt obligations are as follows (in thousands):

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

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

6.14 Other Liabilities and Accounts Payable

	12.31.2023	12.31.2022
	USD '000	USD '000
Accounts payable	4.589	2.399
Total	**4.589**	**2.399**

Other liabilities

	12.31.2023	12.31.2022
	USD '000	USD '000
Warrant liability	-	-
Secured borrowing liability	2.345	2.278
HSOP Deposit liability	511	496
Deferred credit	5062	890
Operating lease liability	990	44
Total	**8.908**	**3.708**

6.15 Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	12.31.2023	12.31.2022
	USD '000	USD '000
Accrued accounting, legal, and other professional fees	5.468	3.566
Taxes payable	715	2.224
Accrued external research and development expenses	3.031	5.550
Accrued payroll	4.941	5.260
Accrued advisory fees	-	-
Other liabilities	1.101	706
Total	**15.256**	**17.306**

7. Notes to the consolidated statement of cash flows

The following table summarizes our cash flows for years ended December 31, 2023 and 2022:

	12.31.2023	12.31.2022
	USD '000	USD '000
Net cash used in operating activities	(84.118)	(104.467)
Net cash used in investing activities	(53.295)	(86.848)
Net cash provided by financing activities	(8.355)	20.784
Effect of foreign exchange rate changes on cash	189	(1.123)
Net increase (decrease) in cash	**(145.579)**	**(171.654)**

Net Cash Used in Operating Activities

Net cash used in operating activities was $84.1 million for the year ended December 31, 2023, which consisted of a net loss attributable to stockholders of $47.3 million, adjusted by noncash benefit of $44.3 million and net cash inflows from the change in operating assets and liabilities of $7.5 million. The noncash benefit primarily consisted of $86.6 million gain related to the net change in the fair value of our assets and liabilities carried at fair value, $0.5 million of other noncash expenses, and $0.1 million gain on deconsolidation of a variable interest entity, partially offset by $36.3 million of stock-based compensation, $3.6 million of losses from our equity method investments, $1.0 million impairment of other investment, $0.8 unrealized foreign exchange losses, and $1.1 million of depreciation and amortization. The net cash inflows from the change in operating assets and liabilities of 7.5 was primarily due to a $8.7 million decrease in prepaid expenses and a $2.1 million increase in accounts payable, partially offset by a $3.3 million decrease in accrued liabilities.

Net cash used in operating activities was $104.5 million for the year ended December 31, 2022, which consisted of a net loss of $152.5 million, adjusted by non-cash charges of $51.5 million and net cash outflows from the change in operating assets and liabilities of $3.5 million. The non-cash charges primarily consisted of $53.4 million of stock-based compensation, $16.3 million of losses from our equity method investments, $0.9 million impairment of loan receivable and $0.4 million of IPR&D considered to have no future alternative use, partially offset by $4.9 million of unrealized foreign exchange gains, $1.5 million gain on deconsolidation of a variable interest entity and $1.5 million gain from the change in fair value of contingent consideration liabilities. The net cash outflows from the change in operating assets and liabilities were primarily due to a $3.0 million decrease in accounts payable and a $1.0 million increase in prepaid expenses, partially offset by a $0.5 million increase in accrued liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $53.3 million for the year ended December 31, 2023, primarily driven by $160.3 million of cash paid for securities carried at fair value, $25.0 million of cash committed in anticipation of the closing of Beckley Psytech investment in January 2024, $3.5 million of loans remitted to related party, $2.0 million of cash paid for convertible notes receivable - related party, $1.0 million of cash paid for investments held at fair value, $0.4 million cash paid out in variable interest entity deconsolidation, $0.3 million of cash paid for capitalized internal-use software development costs, and $0.3 million of cash paid for property and equipment, partially offset by $139.0 million of proceeds from sale and maturities of securities at fair value, and $0.5 million of proceeds from sale of other investments.

Net cash used in investing activities was $86.8 million for the year ended December 31, 2022, primarily driven by $309.1 million of cash paid for securities carried at fair value, $3.0 million of loans remitted to related parties, additional investments of $0.6 million in our other investments, $0.7 million of purchases of property and equipment, and $0.2 million of capitalized internal-use software development costs, partially offset by $226.8 million of proceeds from sale and maturities of securities at fair value.

Net Cash Provided by Financing Activities

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

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

8 Other notes to the financial statements

8.1 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 Investment bank AG ("SMC"). SMC paid a portion of the advisory fees received from the Company to Apeiron.

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, totalling $32.2 million, was automatically converted into 8,773,056 shares of common stock pursuant to their original terms. Once the notes were converted, the converted shares were recorded at fair value of $5.56 per share price equal to the price per share of common stock issued in November 2020.

In January 2021, pursuant to an additional closing from the common stock issuance in November and December 2020, the Company issued and sold 2,133,328 shares of common stock to Apeiron at the same issuance price, for cash proceeds of $12.2 million. In March 2021, the Company issued and sold 13,419,360 shares of common stock to new and existing investors, including related parties, at a price of €9.69 or $11.71 per share, for cash proceeds of $152.2 million, net of issuance costs of $4.9 million.

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

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

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

8.2 Additional Paid in Capital Adjustments upon consolidation

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.

On September 1, 2023, the Company and Cyclica entered into a Stock Transfer Agreement which resulted in the Company's acquisition of Cyclica's 20% equity ownership of EntheogeniX (the "Stock Transfer"). As a result of the "Stock Transfer", the Company owned 100% of the outstanding common stock of EntheogeniX and EntheogeniX became a wholly owned subsidiary of the Company. The Stock Transfer was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of Cyclica's non-controlling interest and the cash paid for the acquisition of the additional equity interest was recorded as a reduction in additional paid-in capital in the condensed consolidated balance sheets and condensed consolidated statements of stockholders' equity.

DemeRx IB, Inc.

In December 2019, DemeRx IB, Inc. ("DemeRx IB") was incorporated as a wholly-owned subsidiary of DemeRx, Inc., formed for the purpose of facilitating a joint venture transaction between DemeRx, Inc. and ATAI AG. DemeRx, Inc. and ATAI AG jointly created DemeRx IB, which was designed to use DemeRx Inc.'s intellectual property to develop Ibogaine as a treatment for opioid dependence.

In October 2023, the Company and DemeRx, Inc. entered into a Stock Purchase and Framework Agreement which resulted in the Company's acquisition of DemeRx, Inc.'s equity ownership of DemeRx IB (the "Stock Purchase"). As a result of the Stock Purchase, the Company owned 100% of the outstanding common stock of DemeRx IB. The Stock Purchase consideration included an $8.0 million upfront cash payment, transfer of the Company's ownership in DemeRx, NB, Inc., settlement of a related term loan, and earn-out consideration contingent upon the achievement of certain development milestones directly related to DemeRx's oral capsule formulation of ibogaine ("DMX-1002") program. At the execution of the Stock Transfer, the earn-out consideration was recorded as a liability at an estimated fair value of $1.3 million and reflected in Contingent consideration in the consolidated balance sheet. The Stock Purchase was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of DemeRx IB's noncontrolling interest and the consideration given for the acquisition of the additional equity interest was recorded as a reduction in Additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

InnarisBio, Inc.
In February 2021, the Company jointly formed InnarisBio, Inc. ("InnarisBio") with UniQuest Pty Ltd ("UniQuest") for the purpose of adding a solgelbased direct-to-brain intranasal drug delivery technology to the Company's platform.

In October 2023, InnarisBio and UniQuest entered into an Assignment, Termination and Release Agreement ("ATRA") which resulted in InnarisBio reacquiring UniQuest's equity interest in exchange for the assignment of intellectual property and the termination of certain license and research agreements. The assigned intellectual property has an approximate fair value of $0.1 million, and the termination of agreements resulted in the extinguishment of a $0.1 million contingent commitment liability. As a result of the ATRA, the Company owned 100% of the outstanding common stock of InnarisBio, and InnarisBio became a wholly owned subsidiary of the Company. The ATRA was accounted for as an equity transaction with no gain or loss recognized. The difference between the carrying amount of InnarisBio's noncontrolling interest and the consideration given for the acquisition of the additional equity interest was recorded as a reduction in Additional paid-in capital in the consolidated balance sheets and consolidated statements of stockholders' equity.

8.3 Earnings 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):

	12.31.2023 USD '000	**12.31.2022** USD '000
Numerator:		
Net loss	(47.260)	(168.469)
Net income (loss) attributable to noncontrolling interests	(3.671)	(5.032)
Net income attributable to atai Life Sciences N.V. shareholders - basic and diluted	(43.589)	(163.437)
Denominator:		
Weighted average common shares outstanding attributable to atai Life Sciences N.V. Stockholders - basic and diluted	158.833.785	155.719.585
Net income per share attributable to atai Life Sciences N.V. shareholders - basic and diluted	(0,27)	(1,05)

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:

	12.31.2023	**12.31.2022**
	USD '000	USD '000
Options to purchase common stock	39.066.454	34.880.604
HSOP options to purchase common stock	6.921.829	6.921.829
2018 Convertible Promissory Notes - Related Parties	2.367.200	6.201.824
2018 convertible promissory notes	3.818.704	-
Unvested restricted stock units	2.944.935	-
	55.119.122	**48.004.257**

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

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

8.4 Defined Contribution Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their annual compensation. Employees may make contributions by having the Company withhold a percentage of their salary up to the Internal Revenue Service annual limit. The Company recognized $0.5 million and $0.5 million of related compensation expense for the years ended December 31, 2023 and 2022.

In other countries the Group operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the Group in an independently administered fund. The pension cost charge disclosed in notes to the financial statements represents contributions payable by the Group to the fund.

8.5 Share based payments

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 cancelled without having been fully exercised will be available for future awards. As of December 31, 2023, there were no shares available for future grants under the 2020 Incentive Plan and any shares subject to outstanding options originally granted under the 2020 Equity Incentive Plan that terminate, expire or lapse for any reason without the delivery of shares to the holder thereof shall become available for issuance pursuant to the atai Life Sciences 2021 Incentive Award Plan discussed below

atai Life Sciences 2021 Incentive Award Plan

Effective April 23, 2021, the Company adopted and the atai shareholders approved the 2021 Incentive Award Plan (“2021 Incentive Plan”). The 2021 Incentive Plan is administered by the Company’s supervisory board. The plan is intended to encourage ownership of shares by employees, directors, and certain consultants to the Company in order to attract and retain such individuals, to induce them to work for the benefit of the Company or of an affiliate and to provide additional incentive for them to promote the success of the Company. The 2021 Incentive Plan enables the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to executive officers, directors and other employees and consultants of the Company.

The Company has reserved up to 55,035,590 shares of common stock, for issuance to executive officers, directors and employees and consultants of the Company pursuant to the 2021 Incentive Plan. In accordance with the evergreen clause in the Company's 2021 Incentive Plan, the number of shares initially available for issuance was increased by 8,033,850 and 8,296,796 shares of common stock effective January 1, 2022 and 2023, respectively. Shares that are expired, terminated, surrendered, or cancelled without having been fully exercised will be available for future awards. As of December 31, 2023, 33,866,036 shares were available for future grants under the 2021 Incentive Plan.

Stock Options

The stock options outstanding noted below consist primarily of both service and performance-based options to purchase Common Stock. These stock options have a ten-year contractual term. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The following is a summary of stock option activity from December 31, 2022 to December 31, 2023:

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

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

(b) Includes 16,751,951 outstanding unvested stock options; (a) 15,138,297 that will continue to vest over a one to four-year service period, (b) 992,654 that will continue to vest over a three to four-year service period and upon the satisfaction of specified performance-based vesting conditions, (c) 137,000 stock options that will continue to vest over a two-year service period, (d) 100,000 stock options that will

continue to vest over a two-year service period and upon the satisfaction of specified market-based conditions tied to price of the Company's publicly traded shares, and (e) 384,000 stock options that will vest on the one-year anniversary of the date of grant.

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

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. For the years ended December 31, 2023 and 2022, the assumptions used in the Black-Scholes option pricing model were as follows:

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

Restricted stock units

The restricted stock units noted below consist of service-based awards vesting over a two-year period, subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company. The Company reflects restricted stock units as issued and outstanding common stock when vested and the shares have been delivered to the individual.

The following is a summary of restricted stock unit activity from December 31, 2022 to December 31, 2023:

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

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 cancelled or forfeited without having been fully exercised will be available for future awards. As of December 31, 2022, 257,419 HSOP Options were available for future grants under the HSOP Plan.

The HSOP Plan mimics the economics of a typical stock option plan, however, with the HSOP Shares to which the HSOP Options refer already being issued to the Partnership. Each HSOP Option contains both service and performance-based vesting conditions, including a liquidity-based condition, and gives the holder the option to request the distribution of HSOP Shares under its vested HSOP Options. The grantee is required to pay a nominal value (€0.06 per share) for the shares upon grant (“Nominal Upfront Payment”). The nominal amount paid at the

grant date is refundable if the HSOP Options do not vest or are forfeited. Otherwise, the nominal amount is refundable until the later of the occurrence of a Liquidity Event (as defined in the "HSOP Plan") or the exercise date.

The HSOP Shares issued under the HSOP Plan to the Partnership are indirectly owned by HSOP Participants (being the holders of HSOP Options) via their interest in the Partnership. However, each HSOP Participant signed a nonrevocable power of attorney ceding virtually all rights and decisions, including their rights as shareholders to the Managing Partner (as defined in the Partnership agreement) of the Partnership. HSOP Participants have a forfeitable right to distributions until the HSOP Options vest, at which time the right becomes nonforfeitable. Accordingly, the HSOP Shares issued to the Partnership and allocated to the HSOP Options holders are not considered outstanding for accounting purposes. Therefore, the Company accounted for the Nominal Upfront Payment as an in-substance early exercise provision as the nominal amount is deducted from the exercise price upon exercise. As of December 31, 2023, the $0.5 million Nominal Upfront Payment was recorded as an Other liability on the consolidated balance sheets. The HSOP Options include a provision that requires the HSOP Options holders pay compensation equal to 2% per annum interest on the unpaid exercise price less the €0.06 nominal amount paid upon grant ("Non-recourse Loan") upon qualifying events (as defined in the Partnership agreement), which occurred on April 23, 2021 currently with the corporate reorganization discussed in Note 1.

The 2% per annum interest rate is fixed and not linked to something other than a service, performance, or market condition, therefore, the Company accounted for the fixed rate interest charge as an in-substance non-recourse loan in a stock compensation arrangement. In such cases, the rights and obligations embodied in a transfer of equity shares to an employee for a note that provides no recourse to other assets or the employee (other than the correlating shares) are substantially the same as those embodied in a grant of share options. The 2% per annum interest was considered in the valuation of the HSOP Options.

HSOP Options

The HSOP Options outstanding noted below consist of service and performance-based options to request the distribution of HSOP Shares. These HSOP Options have a fifteen-year contractual term. These HSOP Options vest over a three to four-year service period, only if and when a "Liquidity Event" (as defined in the Partnership agreement) occurs within fifteen years of the date of grant. If a Change in Control (as defined in the Partnership agreement) or in the event the holder's service with the Partnership is terminated due to his death or disability by June 30, 2021 or December 31, 2021, an additional 25% or 12.5%, respectively, HSOP Options will accelerate and vest upon the occurrence of the transaction. These awards are subject to the risk of forfeiture until vested by virtue of continued employment or service to the Company.

The liquidity-based performance condition contingent upon the achievement of a Liquidity Event was satisfied in June of 2021, therefore, the Company began recognizing expense for all associated options that were previously deemed improbable of vesting.

The following is a summary of stock option activity from December 31, 2022 to December 31, 2023:

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

The Company estimates the fair values of stock options using the Black-Scholes option-pricing model on the date of grant. As shown above, the Company did not grant any new HSOP options during the year ended December 31, 2023 and 2022. For the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense of $3.1 million and $4.5 million, respectively.

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

Subsidiary Equity Incentive Plans

Certain controlled subsidiaries of the Company adopt their own equity incentive plan ("EIP"). Each EIP is generally structured so that the applicable subsidiary, and its affiliates' employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options and restricted stock unit awards under their respective EIP. Standard option grants have time-based vesting requirements, generally vesting over a period of four years with a contractual term of ten years. Such time-based stock options use the Black-Scholes option pricing model to determine grant date fair value.

For the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense of $0.5 million and $0.7 million, respectively, in relation to subsidiary EIPs. As of December 31, 2023, there was $0.2 million of total unrecognized stock-based compensation expense related to unvested EIP awards to employees and non-employee directors expected to be recognized over a weighted-average period of approximately 0.6 years.

Stock-Based Compensation

Stock-based compensation expense is allocated to either Research and development or General and administrative expense on the consolidated statements of operations based on the cost centre to which the option holder belongs.

The following table summarizes the total stock-based compensation expense by function for the year ended December 31, 2023, which includes expense related to stock options and restricted stock awards (in thousands):

	Twelve Months Ended 31 December 2023			
	atai ESOP	**atai HSOP**	**Other Subsidiaries Equity Plan**	**Total**
Research and development	13.260	—	426	13.686
General and administrative	19.569	3.052	39	22.660
Total share-based compensation expense	32.829	3.052	465	36.346

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

	Twelve Months Ended 31 December 2022			
	atai ESOP	**atai HSOP**	**Other Subsidiaries Equity Plan**	**Total**
Research and development	17.974	—	527	18.501
General and administrative	30.208	4.551	167	34.926
Total share-based compensation expense	48.182	4.551	694	53.427

The stock compensation expense disclosed above is $3.4m higher than the expense recognised under US GAAP in the company's 2023 10k report. This is due to a difference in accounting treatment under IFRS versus US GAAP. The change is primarily due to an acceleration of vesting for service only based options.

8.6 Related Party Transactions

atai Formation
In connection with the formation of atai in 2018, the Company entered into a series of transactions with its shareholders, Apeiron, Galaxy Group Investments LLC. ("Galaxy") and HCS Beteiligungsgesellschaft mbH ("HCS") whereby these shareholders contributed their investments in COMPASS, Innoplexus and Juvenescence to the Company in exchange for atai's common stock of equivalent value. Apeiron is the family office of the Company's founder who owns 19.7% and 19.7% of the outstanding common stock in the Company as of December 31, 2023 and 2022, respectively. Galaxy is a NYC-based multi-strategy investment firm that owns 6.5% and 6.5% of the outstanding common stock in the Company as of December 31, 2023 and 2022, respectively.

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

Consulting Agreement with Mr. Angermayer
In January 2021, the Company entered into a consulting agreement, (the "Consulting Agreement"), with Mr. Angermayer, one of the Company's co-founders and supervisory director. Apeiron is the family office and merchant banking business of Mr. Angermayer. Pursuant to the Consulting Agreement, Mr. Angermayer agreed to render services to the Company on business and financing strategies in exchange for 624,000 shares under the 2020 Incentive Plan upon achievement of certain performance targets. The Consulting Agreement expires on March 31, 2024.

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

For the year ended December 31, 2023 and 2022, the Company recorded $0.6 million and $0.6 million, respectively, of stock-based compensation included in general and administrative expense in its consolidated statements of operations related to Mr. Angermayer's service as Chairman of the supervisory board.

8.7 Commitments / License agreements

atai 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 cancellable 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.

8.8 Officers Renumeration

The emolument as referred to in Section 2:383(1) of the Netherlands Civil Code, charged in the financial period to the company can be detailed as follows.

atai's remuneration policy is centred on long-term value creation and the continuity of the Company's business, taking into account the interest of the Company's shareholders, business partners and employees. It aims to successfully recruit, motivate, and retain qualified Managing Directors with the right level of experience and competences to drive the Company's mission. Consequently, this remuneration policy is based on the following principles:

- the remuneration of the Board of Managing Directors is intended to be competitive in relation to both the market in which the Company operates and the nature, complexity, and relative size of the business;

- the fixed and variable pay ratio, the short-term incentive and the long-term incentive all focus on remuneration that recognizes the achievement by the Company and the Managing Directors of agreed targets and delivery of long-term shareholder value creation;
- the remuneration is linked to the experience, role, focus, responsibilities, performance and skills of each Managing Director in order to enhance behaviour required for the successful performance in the existing roles within the Board of Managing Directors; and
- in determining the compensation of the Board of Managing Directors the Dutch Corporate Governance Code has been taken into consideration, as well as the circumstance that the Company is listed at Nasdaq.

The Board of Supervisory Directors of the Company will evaluate the objectives and structure of this remuneration policy at regular intervals, to ensure it is fit for its purpose of delivering the stated objectives. The Board of Supervisory Directors may delegate its authority and responsibility under this policy to its compensation committee.

Remuneration components
The remuneration of the Board of Managing Directors consists of the following components:

- base salary;
- variable compensation (short-term cash incentive);
- long-term equity incentive;
- pension and other benefits;
- and severance pay and benefits.

Base Salaries
The base salaries of the Managing Directors will be determined by the Board of Supervisory Directors and may be based on a market reference group in accordance with the remuneration policy.

Each year, the Board of Supervisory Directors reviews the annual base salaries for Managing Directors and considers whether to adjust base salary levels.

The Board of Supervisory Directors may consider the compensation with comparable qualifications, experience, and responsibilities at companies in similar businesses of comparable complexity, size and success. The Board of Supervisory Directors may also consider the historic salary levels of the individual Managing Director and the nature of the individual Managing Director's responsibilities.

Managing directors will be reimbursed for reasonable business expenses on a charge basis, upon presentation of expense claim forms and always in accordance with the relevant Company policy.

Variable Compensation (Short-Term Incentive)

The objective of this short-term variable compensation is to incentivize the Managing Directors to achieve annual targets and objectives that are related to the short-term focus of the Company.

Targets
Payment of the variable compensation is dependent on the achievement of annual targets and objectives set by the Board of Supervisory Directors based on a proposal of the Compensation Committee. The targets and objectives may include strategic, financial, and operational performance of the Company in line with the corporate objectives as defined for the Company for the applicable year.

Size of variable compensation
The annual cash bonus to be granted to an individual Managing Director shall not exceed 100% of such Managing Director's annual gross base salary unless deviation is in line with the applicable governance rules or the applicable services or employment agreement with the Managing Director.

Additional bonus payments
Notwithstanding clause 3.3., above, the Board of Supervisory Directors may decide, upon a proposal of the Compensation Committee, to increase the cash bonus payable to an individual Managing Director for any given year in case of exceptional achievements of that Managing Director to the extent permitted and in accordance with local rules.

Long-Term Equity Incentive
The objective of the long-term equity incentives is to provide a retention tool for the Managing Directors and to align the long term interests of the Managing Directors and those of the Company and its shareholders.

Furthermore, by granting a long-term incentive in the form of equity, the Managing Directors can participate directly in the growth of the value of the Company to which they contribute.

Targets
The equity awarded to the Managing Directors will be determined by the Board of Supervisory Directors based on the proposal of the Compensation Committee, taking into account market levels and Company-specific circumstances with the intent of creating sustainable long-term shareholder returns.

Grant of equity awards
The Board of Supervisory Directors, based on the proposal of the Compensation Committee, may grant equity awards to the Managing Directors within the framework and subject to the terms and conditions in the Company's equity incentive plan as in effect from time to time.

The terms of the equity awards will be established in award agreements that are consistent with the provisions of the applicable equity plan and entered into with the Managing Directors.

Adjustment and Clawback
If the variable compensation as described above would, in the opinion of the Board of Supervisory Directors, produce an unfair result due to extraordinary circumstances occurring during the performance period, the Board of Supervisory Directors has the power to adjust the value either downwards or upwards.

The Board of Supervisory Directors may also recover from the Managing Directors any variable compensation awarded on the basis of incorrect financial or other data.

Remuneration in the event of a dismissal
The Company may pay severance compensation in accordance with the terms of the Managing Director's contract. The severance compensation shall be in line with relevant market practices, and as well as taking into account that the Company is listed at Nasdaq.

The specific terms of the severance package of a Managing Director will be established in his or her applicable services or employment agreement, which agreement was or will be established within the framework provided in the remuneration policy.

Pensions
Pension provisions that may be provided to Managing Directors will be based upon customary and/or government sponsored pension schemes and in accordance with local law, unless agreed otherwise.

Other benefits
The Company may provide to Managing Directors the opportunity to participate in customary benefit plans programs and arrangements of the Company and its subsidiaries, such as company cars (or a car allowance), medical insurance, accident insurance and relocation allowances, consistent with the terms thereof and as such plans, programs and arrangements may be amended from time to time.

atai's Remuneration policy for the board of Managing Directors can be found here: https://www.sec.gov/Archives/edgar/data/1840904/000119312521188243/d39052dex1024.htm

Remuneration Summary

This section discusses the material components of the executive compensation program for our executive officers. The executive officers are all considered the key management personnel, including the two Managing Directors. In 2023 & 2022, key "named executive officers" and their positions were as follows:

- Florian Brand, Chief Executive Officer;
- Srinivas Rao, MD, PhD, Chief Scientific Officer; and
- Stephen Bardin, Chief Financial Officer.

Key Personnel Remuneration

	31.12.2023 USD '000	31.12.2022 USD '000
Short-term employee benefits	2.280	2.527
Post-employment benefits	25	24
Other long-term benefits	-	-
Termination benefits	-	-
Share-based payments	4.116	9.623
Total	**6.421**	**12.174**

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years presented.

Name and Principal Position[1]	Year	Salary ($)	Bonus ($)[2]	Option Awards ($)[3]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)[4]	Total ($)
Florian Brand, *Chief Executive Officer*	2023	550,000	233,750	2,234,000	—	9,575	3,027,325
	2022	550,000	275,000	3,420,889	—	10,442	4,256,331
Srinivas Rao, MD, PhD, *Chief Scientific Officer*	2023	550,000	233,750	941,000	—	57,094	1,781,844
	2022	550,000	275,000	2,736,711	—	50,535	3,612,246
Stephen Bardin[5] *Chief Financial Officer*	2023	440,000	149,600	941,000		69,880	1,600,480
	2022	183,333	66,542	2,280,000	100,000	42,448	2,672,324

(1) All amounts shown for Mr. Brand and all 2022 amounts shown in "Option Awards" column for all named executive officers were paid or calculated, as applicable, in Euros and converted to U.S. Dollars using the exchange rate in effect on the applicable grant date for purposes of the "Option Awards" columns and the exchange rate in effect on the applicable payment date for purposes of the other columns for Mr. Brand.

(2) Amounts represent performance-based annual cash bonuses for the named executive officers for fiscal year 2023. In addition, $100,000 shown for Mr. Bardin represents a one-time cash sign on bonus paid in connection with his commencement of employment during 2022.

(3) Amounts reflect the grant-date fair value of HSOP Shares (as defined below) and stock options, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of HSOP Shares and stock options granted to our named executive officers in Note 8.8 to the consolidated financial statements in our Annual Report for the year ended 31 December 2023.

(4) The amount shown for Mr. Brand includes contributions to a German pension scheme and private insurance premiums. The amount shown for Dr. Rao includes matching contributions under our 401(k) plan. The amount shown for Mr. Bardin includes

matching contributions under our 401(k) plan relocation stipend and paid paternity leave from October 2023 through December 2023.

(5) Mr. Bardin commenced employment with us as the Deputy Chief Financial Officer and Chief Financial Officer Designate, effective as of June 27, 2022 and was appointed as the Chief Financial Officer, effective as of August 16, 2022.

Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. In connection with our initial public offering in June 2021, our management board approved increases to the annual base salaries of our named executive officers as set forth in the following table. No other changes were made to the base salaries of our named executive officers during 2023.

Name	2023 Annual Base Salary	2022 Annual Base Salary
Florian Brand	$550,000	$550,000
Srinivas Rao, M.D., Ph.D.	$550,000	$550,000
Stephen Bardin	$440,000	$440,000

Cash-Based Incentive Compensation

We provide annual bonuses designed to motivate and reward our executives, including our named executive officers, for achievements relative to certain company performance metrics for the year. Each named executive officer's target bonus opportunity is expressed as a percentage of annual base salary.

Following the end of each year, our supervisory board determines the bonus amounts for our executives, including our named executive officers. For 2023, the supervisory board determined to award bonuses for all employees, including our named executive officers, at 100% of target based upon the company's overall positive performance for the year.

The bonuses awarded to our named executive officers for 2023 performance are set forth above in the 2023 Summary Compensation Table in the column entitled "Bonus."

Equity Compensation

Our named executive officers have been granted options to purchase our common shares. Options typically vest as to 25% of the shares subject to the option on the first anniversary of the applicable vesting commencement date and as to the remaining 75% of the shares subject to the option in 36 substantially equal monthly instalments thereafter until the fourth anniversary of the vesting commencement date, subject to accelerated vesting upon a change in control or in the event the named executive officer's service with the company is terminated due to his death or disability. Certain options granted to our named executive officers have been granted with performance-based vesting conditions. Options granted prior to our initial public offering were not exercisable prior to (1) the fourth anniversary of the date of grant and (2) the occurrence of a liquidity event, subject, in each case, to continued service through such date. Following our initial public offering, these conditions to exercisability are no longer applicable.

Other Elements of Compensation

Retirement Plans

atai Life Sciences US, Inc. maintains a 401(k) retirement savings plan for its employees employed in the United States who satisfy certain eligibility requirements. Our named executive officers in the United States are eligible to participate in the 401(k) plan on the same terms as other full-time employees. Currently, we match 100% of

employee contributions to the 401(k) plan, up to 3% of eligible compensation, and these matching contributions are fully vested as of the date on which the contribution is made. We believe that providing a vehicle for tax-deferred retirement savings to our employees in the United States adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. We did not maintain any private pension or retirement plans for our employees employed in Germany during 2023.

Employee Benefits and Perquisites

All of our full-time employees in the United States, including our named executive officers, are eligible to participate in our health and welfare plans, including, medical, dental and vision benefits, short-term and long-term disability insurance, and life insurance. Prior to our initial public offering, we reimbursed (or directly paid) 80% of the premium payments for our executive officers, including our named executive officers, for coverage under these plans, which was greater than the amounts paid for our other full-time employees. Following our initial public offering, we reimburse or directly pay 100% of the premium payments for coverage under these plans for all of our employees.

During 2023, Mr. Brand was entitled to reimbursement for contributions paid by him for private health and long-term care insurance, not to exceed $960 per month. The amounts paid pursuant to these arrangements during 2023 were less than $10,000 in the aggregate for each named executive officer.

Pay Ratio

The Executive Board to employee pay-ratio is approximately 2.9 (2022: 4.4). This pay ratio is based on the average of the 2023 Executive Board remuneration including pensions and other expenses (as disclosed in this note) and the average wage costs per FTE in 2023 calculated using total Personnel Expense (note 5.5) and the employee headcount detail (note 5.4) within this Annual Report.

8.9 Remuneration of the Board of Directors

In connection with our initial public offering. we adopted a two-tier board structure consisting of a management board and a supervisory board and are no longer managed by the board of atai Life Sciences AG following our initial public offering.

Our shareholders have approved a remuneration policy for our supervisory board pursuant to which our supervisory directors may be entitled to cash and equity compensation in such amounts necessary to attract and retain supervisory directors that have the talent and skills to foster long-term value creation and enhance the sustainable development of the company. The compensation payable under the policy is intended to be competitive in relation to both the market in which the company operates and the nature. complexity and size of the company's business. The supervisory directors currently receive the following amounts for their services on our supervisory board:

- Upon the director's initial election or appointment to our supervisory board, an option to purchase 128,000 common shares;
- If the director has served on our supervisory board for at least six months as of the date of an annual meeting of shareholders and will continue to serve as a director immediately following such meeting, an option to purchase 64,000 common shares on the date of the annual meeting;
- An annual director fee of $40,000.

Director fees are payable in arrears in four equal quarterly instalments not later than the thirtieth day following the final day of each calendar quarter, provided that the amount of each payment is prorated for any portion of a quarter that a director is not serving on our supervisory board.

Options granted to non-employee directors have an exercise price equal to the fair market value of a common share on the date of grant and expire not later than ten years after the date of grant. Options granted upon a director's initial election or appointment vest as to one-third of the shares on the first

anniversary of the date of grant and in twenty-four (24) substantially equal monthly instalments thereafter until the third anniversary of the date of grant. Options granted annually to directors vest in a single instalment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested options vest in full upon the occurrence of a change in control.

The following table sets forth information concerning the compensation of non-employee members of our board for service on the board for the year ended 31 December 2023.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(2)	Total ($)
Christian Angermayer	70,000	88,960	158,960
Michael Auerbach	70,000	88,960	158,960
Jason Camm(1)	40,000	88,960	128,960
Sabrina Martucci Johnson	63,000	88,960	151,960
Amir Kalali, M.D.	51,500	88,960	140,460
Andrea Heslin Smiley	61,500	88,960	150,460

(1) Due to his association with Thiel Capital LLC,, Mr. Camm had previously waived his right to receive compensation for serving on our supervisory board. At the end of 2022 Mr. Camm was no longer associated with Thiel Capital compensation started Q1 2023.

(2) Amounts reflect the full grant-date fair value of stock options, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all stock options granted to our supervisory board members in Note 8.2 to the consolidated financial statements in our Annual Report for the year ended 31 December 2023.

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2023 by each non-employee director. None of the non-employee directors held any unvested stock awards in us as of December 31, 2023.

Name	Options Outstanding at Fiscal Year End
Christian Angermayer	880,000
Michael Auerbach	256,000
Jason Camm	64,000
Alexis de Rosnay(1)	192,000
Sabrina Martucci Johnson	256,000
Amir Kalali, M.D.	256,000
Andrea Heslin Smiley	256,000

(1) Mr. de Rosnay resigned from the supervisory board effective November 2, 2022.

8.10 Corporate Restructuring

In February 2023, the Company restructured its workforce and eliminated approximately 30% of its global workforce in order to more effectively allocate its research and development and other resources supporting the revised business and program priorities and to reduce operational costs.

Restructuring expense related to the workforce reduction was incurred primarily during the year ended December 31, 2023, resulting in $3.2 million of restructuring expense, which consisted of $3.0 million of cash expenditures for severance and other employee separation-related costs and $0.2 million of stock-based compensation expense. Of the restructuring expense, for the year ended December 31, 2023, $1.8 million and $1.4 million were recorded in research and development expenses and general and administrative expenses, respectively, in the consolidated statement of operations.

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

8.11 Subsequent Events

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

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

The Company had paid $25 million into BPL's legal counsel's trust account in anticipation of the January execution. All funds were transferred to BPL upon execution.

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

In March 2024, the Company and IntelGenx entered into a third amended and restated loan agreement, pursuant to which, among other things, the Company made a $1.0 million additional term loan following the execution and has agreed to make an additional $1.0 million term loan to be disbursed upon the achievement of a pre-defined milestone.

In January 2024, the Company and Mr. Angermayer entered into the Termination and New Consultancy Agreement (the "2024 Consultancy Agreement"). Pursuant to the 2024 Consultancy Agreement, the parties agreed to terminate the Consultancy Agreement (as defined above) between ATAI AG and Mr. Angermayer dated January 16, 2021 (the "Original Consultancy Agreement") and enter into a new consultancy agreement between the Company and Mr. Angermayer to, among other things, extend the term of the Original Consultancy Agreement to January 5, 2028, increase the services to include various business objectives (including related to business and finance, communication and investor relations), and provide for the grant of an option to purchase 1,658,094 shares of the Company that vests over four years in part based on continued service and in part based on the Company's total shareholder return compared to the four-year total shareholder return of the companies comprising the XBI.

In April 2024, Apeiron and ATAI Life Sciences NV executed an exchange agreement ("2024 Exchange Agreement") where Apeiron agreed to exchange its 2020 convertible notes issued by ATAI Life Sciences AG (the "Old AG Notes") into the same principal amount and number of new convertible notes issued by ATAI Life Sciences N.V. (the "New NV Notes") subject to the same financial terms and conditions for no additional consideration. The New NV Notes are non-interest-bearing, unsecured and are due and payable on September 30, 2025, unless previously redeemed, converted, purchased or cancelled (the "Maturity Date"). Each New NV Note has a face value of €1.00 and is convertible into 16 common shares of ATAI Life Sciences N.V. upon the payment of €17.00 per New NV Note. Conversion rights may be exercised by a noteholder at any time prior to the Maturity Date. The New NV Notes may be declared for early redemption by the noteholders upon occurrence of specified events of default, including failing to deliver shares upon conversion, insolvency and a material adverse change in the Company's business, operations or financial or other condition. Upon early redemption, the conversion right with respect to the New NV Notes may no longer be exercised. Apeiron is Mr. Angermayer's family office.

COMPANY FINANCIAL STATEMENTS

Company balance sheet, after appropriation of result

(In USD thousands, except per share amounts)

	Notes	12.31.2023	12.31.2022
		atai N.V.	atai N.V.
Assets			
Non-Current Assets			
Investments	**5**	196.117	52.588
Financial fixed assets	**6**	13.584	15.812
Total non-current assets		**209.701**	**68.400**
Current assets			
Cash and cash equivalents		553	138.186
Securities held at fair value	**7**	54.245	73.604
Prepaid expenses and other current assets		1.675	2.254
Total current assets		**56.473**	**214.044**
Total assets		**266.174**	**282.444**
Equity and liabilities			
Equity	**8**		
Share Capital		18.573	18.562
Share premium		809.204	785.144
Share subscription receivable		-	(24)
Accumulated Deficit		(565.355)	(521.240)
FX Reserve		(19.460)	(21.702)
Total Stockholders' equity		**242.962**	**260.740**
Liabilities			
Current liabilities:			
Accrued Liabilities		4.676	2.605
Total current liabilities		**4.676**	**2.605**
Non-Current liabilities:			
Long term debt	9	15.047	14.702
Other liabilities	10	3.489	4.397
Total liabilities and stockholders' equity		**266.174**	**282.444**

Company only profit and loss account

(In USD thousands, except per share amounts)

	Note	Year ended 31 December 2023	Year ended 31 December 2022
Loss for the period		(21.501)	(24.244)
Share of result of participating interests after tax	**5**	(22.088)	(139.193)
Net loss		(43.589)	(163.437)

Notes to the company only financial statements

1. General company information

These Company only financial statements, and the consolidated financial statements together constitute the statutory financial statements of atai Life Sciences N.V. (hereafter: 'the Company'). The financial information of the Company is included in the Company's consolidated financial statements.

atai has its registered office and its actual place of business at Wallstraße 16, 10179 Berlin, Germany. Its statutory seat is in Amsterdam, Netherlands, and the company is registered in the Trade Register at the Chamber of Commerce under number CvC 80299776.

2. Basis of preparation

These Company only financial statements have been prepared in accordance with Title 9, Book 2 of the Netherlands Civil Code. As from 1 January 2021 the Company makes use of the option provided in section 2:362(8) of the Dutch Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting principles as described in the consolidated financial statements. For an appropriate interpretation of these company financial statements, the company financial statements should be read in conjunction with the consolidated financial statements.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

All amounts in the company financial statements are presented in USD thousand, unless stated otherwise. Financial information presented has been rounded to the nearest thousand. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them or may deviate from other tables by one thousand euros at a maximum.

3. Participating interests in group companies

Group companies are all entities in which the Company has directly or indirectly control. The Company controls an entity when it is exposed, or has rights, to variable returns from its involvement with the group companies and has the ability to affect those returns through its power over the group companies. Group companies are recognised from the date on which control is obtained by the Company and derecognised from the date that control by the Company over the group company ceases. Participating interests in group companies are accounted for in the separate financial statements according to the equity method, with the principles for the recognition and measurement of assets and liabilities and determination of results as set out in the notes to the consolidated financial statements.

4. Share of result of participating interests

The share in the result of participating interests consists of the share of the Company in the result of participating interests. Results on transactions involving the transfer of assets and liabilities between the Company and its participating interests are eliminated to the extent that they can be considered as not realised.

5. Investments

Investments include the 100% investment of the Company in its fully owned subsidiaries atai Life Sciences AG and atai Holdco, Inc. atai Holdco, Inc was a newly created entity in 2023

The group is deemed to have control via voting shares and several other indicators such a board presence and agreements in place providing control over financial and operating policies of the subsidiaries.

As of December 31, 2023 and December 31, 2022, the carrying values of other investments were as follows (in thousands):

	12.31.2023	12.31.2022
	USD '000	USD '000
atai Life Sciences AG	94.942	52.588
Atai Holdco, Inc	101.175	-
Total	**196.117**	**52.588**

Investment rollforward

	atai Life Sciences AG	Atai Holdco, Inc	Total
Balance as of 1st January 2023	52.588	-	52.588
Capital contribution	65.442	100.175	165.617
Share of result of participating interests after tax	(23.088)	1.000	(22.088)
Balance as of 31 December 2023	**94.942**	**101.175**	**196.117**

During 2023, atai Holdco, Inc was incorporated as a new wholly owned subsidiary of atai Life Sciences NV. This entity is part of the ongoing simplification and reorganisation efforts of atai to streamline its operations.

6. Financial fixed assets

Financial fixed assets include group undertakings of $12.7m held with ATAI Life Sciences AG.

7. Securities held at fair value

The Company elected the fair value option for the securities in its investment portfolio (level 2). The fair value is based on quoted market prices, when available. When a quoted market price is not readily available, the Company uses the market price from its last sale of similar assets.

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

The unrealized gains and losses on the available-for-sale securities, represented by change in the fair value of the investment portfolio, is reported in earnings. Since the investment in the available-for-sale securities are already measured at fair value, no separate credit losses would be recorded in the financials.

For the year-ended December 31, 2023 and 2022, the Company recognized a $3.9 million and $0.1 million gain related to the change in fair value change in its available for sale securities recorded as a Change in fair value of assets and liabilities, net in its consolidated statements of operations.

8. Shareholders' equity

For the company statement of changes in equity, we refer also to Consolidated Financial Statements.

Called up capital and share premium

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 16 to one, and the nominal value of the shares was reduced to €0.10 EUR, pursuant to a shareholders' resolution and amendment to the articles of association. The nominal share value was converted into USD on June 22, 2021 at a rate of 0.8333 EUR/USD to give a value of $0.12 USD.

Proposal for result appropriation

The General Meeting will be proposed to carry forward the loss after tax for 2023 and deduct USD $43.589m from the other reserves.

The result after tax for 2023 is included in the item retained earnings within equity.

9. Long term debt

Long term debt is the Hercules Loan and Security Agreement. For an overview of this agreement, we refer to note 6.13 of the consolidated financial statements.

10. Other liabilities

Other liabilities includes $2.6m of Convertible promissory notes that were originally held in ATAI Life Sciences AG.

For an overview of the convertible promissory notes, we refer to note 6.12 of the consolidated financial statements.

11. Financial instruments

The Company's principal financial assets comprise short-term deposits at commercial banks. The main purpose of these financial instruments is to provide funds for the subsidiaries development activities. The Company's other financial instruments relate to other receivables and liabilities.

The risks associated with the Company financial instruments are similar to the ones disclosed in notes to the consolidated financial statements.

12. Key Management Personnel

The emolument as referred to in Section 2:383(1) of the Netherlands Civil Code, charged in the financial period to the company is referenced in Key Management Personal compensation, notes 8.8 and 8.9 of the consolidated financial.

13. Subsequent Events

Information regarding events after the balance sheet date can be found in various Notes to the Consolidated Financial Statements, as applicable, included herein. There have been no significant events that warrant the inclusion of a separate.

OTHER INFORMATION

STATUTORY RULES CONCERNING APPROPRIATION OF PROFIT

In the company's articles of association the following has been presented concerning the appropriation of profits & reserves:

32 DISTRIBUTIONS – GENERAL

32.1 A distribution can only be made to the extent that the Company's equity exceeds the amount of the paid up and called up part of its capital plus the reserves which must be maintained by law.

32.2 The Board of Managing Directors may resolve to make interim distributions, provided that it appears from interim accounts to be prepared in accordance with Section 105 paragraph 4 Book 2 that the requirement referred to in Article 32.1 has been met.

32.3 Distributions shall be made in proportion to the aggregate par value of the Shares.

32.4 The parties entitled to a distribution shall be the relevant Shareholders, usufructuaries and pledgees, as the case may be, at a date to be determined by the Board of Managing Directors for that purpose. This date shall not be earlier than the date on which the distribution was announced.

32.5 The General Meeting may resolve, subject to Article 28, 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 the Company's assets.

32.6 A distribution shall be payable on such date and, if it concerns a distribution in cash, in such currency or currencies as determined by the Board of Managing Directors. If it concerns a distribution in the form of the Company's assets, the Board of Managing Directors shall determine the value attributed to such distribution for purposes of recording the distribution in the Company's accounts with due observance of applicable law (including the applicable accounting principles).

32.7 A claim for payment of a distribution shall lapse after five years have expired after the distribution became payable.

32.8 For the purpose of calculating the amount or allocation of any distribution, Shares held by the Company in its own capital shall not be taken into account. No distribution shall be made to the Company in respect of Shares held by the Company in its own capital.

33 DISTRIBUTIONS - PROFITS AND RESERVES

33.1 Subject to Article 32.1, the profits shown in the Company's annual accounts in respect of a financial year shall be appropriated as follows, and in the following order of priority:

a. the Board of Managing Directors shall determine which part of the profits shall be added to the Company's reserves; and
b. subject Article 28.1, the remaining profits shall be at the disposal of the General Meeting for distribution on the Shares.

33.2 Subject to Article 32.1, a distribution of profits shall be made after the adoption of the Annual Accounts that show that such distribution is allowed.

33.3 Subject to Article 28, the General Meeting is authorised to resolve to make a distribution from the Company's reserves.

33.4 The Board of Managing Directors may resolve to charge amounts to be paid up on Shares against the Company's reserves, irrespective of whether those Shares are issued to existing Shareholders.

INDEPENDENT AUDITOR'S REPORT

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INDEPENDENT AUDITOR'S REPORT

To the shareholders and the Supervisory Board of ATAI Life Sciences N.V.

Report on the audit of the financial statements 2023 included in the annual report

Our opinion

We have audited the financial statements 2023 of ATAI Life Sciences N.V. statutory seated in Amsterdam. The financial statements comprise the consolidated financial statements and the company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of ATAI Life Sciences N.V. as at 31 December 2023, and of its result and its cash flows for 2023 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.

- The accompanying company financial statements give a true and fair view of the financial position of ATAI Life Sciences N.V. as at 31 December 2023, and of its result for 2023 in accordance with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements comprise:

1. The consolidated statement of financial position as at 31 December 2023.

2. The following statements for 2023: the consolidated statement of profit & loss, consolidated statements of other comprehensive income (loss), consolidated statements of financial position, consolidated statements changes in equity and consolidated statements of cash flows.

3. The notes comprising material accounting policy information and other explanatory information.

The company financial statements comprise:

1. The company balance sheet as at 31 December 2023.

2. The company profit and loss account for 2023.

3. The notes comprising a summary of the accounting policies and other explanatory information.

Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the 'Our responsibilities for the audit of the financial statements' section of our report.

Deloitte.

We are independent of ATAI Life Sciences N.V. in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta, Audit firms supervision act), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Information in support of our opinion

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion was addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

Materiality

Based on our professional judgement we determined the materiality for the financial statements as a whole at USD 4,300,000 (2022: USD 5,000,000). The materiality is based on operating expenses. We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

Scope of the group audit

ATAI Life Sciences N.V. is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements of ATAI Life Sciences N.V.

Our group audit mainly focused on significant group entities. Our assessment of entities that are significant to the group was done as part of our audit planning and was aimed to obtain sufficient coverage of the risks of a material misstatement for the significant account balances, classes of transactions and disclosures that we have identified.

By performing the procedures mentioned above at group entities, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion on the consolidated financial statements.

Audit approach fraud risks

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the entity and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control and how the Supervisory Board exercises oversight, as well as the outcomes.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as among others the code of conduct, whistle blower procedures and incident registration. We evaluated the design and the implementation of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption. We evaluated whether these factors indicate that a risk of material misstatement due fraud is present.

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We identified the presumed fraud risk of management override of controls as a significant fraud risk in our audit. We performed, amongst others, the following specific procedures:

- We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

- We considered available information and made enquiries of relevant executives (such as the chief executive officer, chief financial officer and chief scientific officer), directors (including the chief accounting officer), other accounting personnel, general counsel and the Management Board.

- We tested the appropriateness of journal entries recorded in the general ledger and other adjustments made in the preparation of the financial statements.

- We evaluated whether the selection and application of accounting policies by the entity, particularly those related to subjective measurements and complex transactions, may be indicative of fraudulent financial reporting.

- We evaluated whether the judgments and decisions made by management in making the accounting estimates included in the financial statements indicate a possible bias that may represent a risk of material misstatement due to fraud. Management insights, estimates and assumptions that might have a major impact on the financial statements are disclosed in note 3 of the financial statements.

- For significant transactions, we evaluated whether the business rationale of the transactions suggests that they may have been entered into to engage in fraudulent financial reporting or to conceal misappropriation of assets.

The above mentioned procedures did not lead to indications for fraud potentially resulting in material misstatements.

Audit approach compliance with laws and regulations

We assessed the laws and regulations relevant to the entity through discussion with management, general counsel and other relevant personnel within the entity, as well as by reading the minutes of the Management Board.

As a result of our risk assessment procedures, and while realizing that the effects from non-compliance could considerably vary, we considered the following laws and regulations: (corporate) tax law and financial reporting regulations, the requirements under the International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and Part 9 of Book 2 of the Dutch Civil Code and laws and regulations specifically applicable to listed companies with a direct effect on the financial statements as an integrated part of our audit procedures, to the extent material for the financial statements.

We obtained sufficient appropriate audit evidence regarding provisions of those laws and regulations generally recognized to have a direct effect on the financial statements.

Apart from these, the entity is subject to other laws and regulations, including laws and requirements established by authorities such as the FDA or EMA, where the consequences of non-compliance could have a material effect on amounts and/or disclosures in the financial statements, for instance, through imposing fines or litigation.

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Given the nature of the entity's business and the complexity of these other laws and regulations, there is a risk of non-compliance with the requirements of such laws and regulations. In addition, we considered major laws and regulations applicable to listed companies.

Our procedures are more limited with respect to these laws and regulations that do not have a direct effect on the determination of the amounts and disclosures in the financial statements. Compliance with these laws and regulations may be fundamental to the operating aspects of the business, to the entity's ability to continue its business, or to avoid material penalties (e.g., compliance with the terms of operating licenses and permits or compliance with environmental regulations) and therefore non-compliance with such laws and regulations may have a material effect on the financial statements. Our responsibility is limited to undertaking specified audit procedures to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements. Our procedures are limited to (i) inquiry of management, the Supervisory Board, the Executive Board and others within the entity as to whether the entity is in compliance with such laws and regulations and (ii) inspecting correspondence, if any, with the relevant licensing or regulatory authorities to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements.

Naturally, we remained alert to indications of (suspected) non-compliance throughout the audit.

Finally, we obtained written representations that all known instances of (suspected) fraud or non-compliance with laws and regulations have been disclosed to us.

Audit approach going concern

Under the going concern basis of accounting, the financial statements are prepared on the assumption that the entity is a going concern and will continue its operations for the foreseeable future. The company is of the opinion that, based on the current state of affairs, it is justified that the financial statements are prepared on a going concern basis.

Since ATAI Life Sciences N.V. is a clinical-stage biopharmaceutical company, the Company is not generating material revenues in 2023. We've have evaluated management's assessment of the Company's ability to continue as a going concern. In evaluating management's assessment, we considered whether management's assessment includes all relevant information of which we are aware as a result of the audit.

We have evaluated the Company's going concern assessment and performed (amongst others) the following procedures:

- Analyzing and discussing cash flows, including cash burn analysis and other relevant forecasts with management.
- Analyzing and discussing the entity's latest available internal reporting.
- Reading minutes of the Annual General Meeting of Shareholders, those charged with governance and relevant committees for reference to financial difficulties.
- Performing audit procedures regarding subsequent events to identify those that either mitigate or otherwise affect the entity's ability to continue as a going concern.

Based on the procedure performed we concur with management's evaluation.

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Our key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the Supervisory Board. The key audit matters are not a comprehensive reflection of all matters discussed. These matters were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

The following key matter has been communicated.

<table>
<tr><th colspan="2">1. Direction and supervision of Deloitte & Touche LLP</th></tr>
<tr><th>DESCRIPTION</th><th>HOW THE KEY AUDIT MATTER WAS ADDRESSED IN THE AUDIT</th></tr>
<tr><td rowspan="3">On 22 June 2021, ATAI Life Sciences N.V. closed the initial public officering (“IPO”) of the common shares on the Nasdaq Stock Market (“Nasdaq”). As a result of this listing on the Nasdaq, the Company issues it’s 10-K Annual Report for which Deloitte & Touche LLP provides a report as independent registered public accounting firm.

As ATAI Life Sciences N.V. is statutory seated in Amsterdam, The Netherlands, ATAI is required to issue financial statements prepared in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code. Deloitte Accountants B.V. has been appointed as the Company’s auditor since 2021.

Following the N.V. structure of the group, we as Deloitte Accountants B.V., are required by International Standard on Auditing 600 to direct, supervise and review the work that was performed by Deloitte & Touche LLP. The direction, supervision and review of the work that was performed by Deloitte & Touche LLP forms a significant part of our audit and therefore we have identified this as a key audit matter.</td><td>We have performed the following audit procedures:

• We issued written instructions to the audit team of Deloitte & Touche LLP. We reviewed and discussed the audit team’s deliverables to ensure the work was performed in accordance with our instructions.

• In addition, we exercised direction, supervision and review on the work performed by the audit team of Deloitte & Touche LLP throughout all stages of the audit by means of remote meetings, site visits as well as physical and remote file reviews. During these interactions, we were involved in the direction, supervision and review of audit procedures, such as but not limited to, risk assessment, evaluating the company’s internal control environment, (fraud) risk assessment, substantive audit procedures on significant and higher risk areas, accounting matters such as the transactions and concluding audit procedures.

• We have joined several interactions between the audit team of Deloitte & Touche LLP and management of ATAI Life Sciences N.V. on significant accounting and audit matters, including several audit committee meetings.</td></tr>
<tr><td>OBSERVATION</td></tr>
<tr><td>The scope and nature of the procedures performed were appropriate and sufficient to address the key audit matter. Our procedures did not result in any reportable matters.</td></tr>
</table>

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Report on the other information included in the annual report

The annual report contains other information, in addition to the financial statements and our auditor's report thereon.

The other information consists of:

- Management Board's Report.
- Other Information as required by Part 9 of Book 2 of the Dutch Civil Code.

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements.
- Contains all the information regarding the management report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

Management is responsible for the preparation of the other information, including the Management Board's Report in accordance with Part 9 of Book 2 of the Dutch Civil Code, and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

Report on other legal and regulatory requirements

Engagement

We were engaged by the Supervisory Board as auditor of ATAI Life Sciences N.V. on 17 June 2022, as of the audit for the year 2021 and have operated as statutory auditor ever since that financial year.

No prohibited non-audit services

We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

Description of responsibilities regarding the financial statements

Responsibilities of Management and the Supervisory Board for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, management is responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

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As part of the preparation of the financial statements, management is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

Management should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Supervisory Board is responsible for overseeing the company's financial reporting process.

Our responsibilities for the audit of the financial statements

Our objective is to plan and perform the audit assignment in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgement and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included among others:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- Concluding on the appropriateness of management's use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.

- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures.

- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

We communicate with management regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identified during our audit. In this respect we also submit an additional report to the audit committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report.

We provide the Supervisory Board with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Supervisory Board, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Utrecht, 22 April 2024

Deloitte Accountants B.V.

Signed on the original: R. Dekker